IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF NEW YORK

DR. A., NURSE A., DR. C., NURSE D., DR. F., DR. G, THERAPIST I., DR. J., NURSE J., DR. M., NURSE N., DR. O., DR. P., TECHNOLOGIST P., DR. S., NURSE S. and **PHYSICIAN LIAISON X.**, Plaintiffs, v. **KATHY HOCHUL**, Governor of the State of New York, in her official capacity; **HOWARD A. ZUCKER**, Commissioner of the New York State Department of Health, in his official capacity; and **LETITIA JAMES**, Attorney General of the State of New York, in her official capacity, Defendants.	)	Case No. 1:21-cv-1009 (DNH/ML)

VERIFIED COMPLAINT

Plaintiffs herein, proceeding under pseudonyms for the reasons set forth below, complain of the Defendants as follows:

NATURE OF ACTION

1. This action seeks injunctive and declaratory relief from a New York State Department of Health (DOH) regulation, promulgated on August 26, 2021, that purports to nullify Title VII and the parallel protections of the New York State Human Rights Law and the New York City Human Rights Law by mandating the COVID-19 vaccination of health care professionals with no exemption for sincere religious beliefs that compel the refusal of such vaccination (the "Vaccine Mandate").

2. This "emergency" regulation, promulgated almost three months after the former Governor of New York *ended* the COVID-related "state disaster emergency" and rescinded all his pertinent executive orders, negates even the protection for sincere religious beliefs in a prior DOH regulation promulgated only days before, when the former Governor was still in office.

3. Plaintiffs have moved this Court for temporary and preliminary injunctive relief in view of the September 27, 2021 deadline for compliance with the Vaccine Mandate, after which plaintiffs, whose religious beliefs compel abstention from COVID-19 vaccination, will be harmed irreparably by loss of employment and professional standing.

JURISDICTION AND VENUE

4. This action arises under the First and Fourteenth Amendments to the United States Constitution and is brought pursuant to 42 U.S.C. § 1983. This action also arises under federal statutory laws, namely 42 U.S.C. § 1985(3) and 42 U.S.C. § 2000e-2

5. This Court has jurisdiction over the instant matter pursuant to 28 U.S.C. §§ 1331 and 1343.enue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2) because two of the defendants reside in this District and a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this District.

6. This Court is authorized to grant declaratory judgment under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, implemented through Rule 57 of the Federal Rules of CivilProcedure.

7. This Court is authorized to grant Plaintiffs' prayer for temporary, preliminary, and permanent injunctive relief pursuant to Rule 65 of the Federal Rules of CivilProcedure.

8. This Court is authorized to grant Plaintiffs' prayer for relief regarding costs, including a reasonable attorney's fee, pursuant to 42 U.S.C. § 1988.

THE PARTIES

Plaintiffs

9. As more particularly alleged below, the plaintiffs herein are medical professionals whose sincere religious beliefs compel them to refuse vaccination with the available COVID-19 vaccines, all of which employ aborted fetus cell lines in their testing, development, or production.

10. All of the plaintiffs are employed by entities with 15 more employees covered by Title VII, which mandates the reasonable accommodation of sincere religious beliefs. Eight of the seventeen plaintiffs reside and work in this District, while the others reside and/or work variously in the Southern, Eastern and Western Districts.

Defendants

11. Defendant Kathy Hochul (Hochul) is Governor of the State of New York who, as the State's chief executive, is responsible for the execution of its laws and regulations, including the challenged vaccine mandate, and for the approval of all executive branch policies and directives, including those of the DOH pertaining to the vaccine mandate. At all pertinent times Hochul has acted and will act under color of state law. Defendant Hochul's principal place of business is located at the State Capitol Building, Albany, New York. She is sued in her official capacity.

12. Defendant Howard A. Zucker (Zucker) is Commissioner of Health for the DOH. He is responsible for promulgation and enforcement of the challenged vaccine mandate. At all pertinent times Zucker has acted and will act under color of state law. Defendant Zucker's principal place of business is located at 3959 Broadway, New York, NY 10032. He is sued in his official capacity.

13. Defendant LETITIA JAMES (James) is the Attorney General for the State of New York, the State's highest-ranking law enforcement officer charged with overall supervision of the enforcement of the challenged vaccine mandate and other laws of the State of New York. At all times relevant to this Complaint, James is and was acting under color of State law. Defendant James' principal place of business is located at the State Capitol Building, Albany, New York. She is sued in her official capacity.

BACKGROUND

> "*No one should be forced to be vaccinated against their will* both because of *the constitutional right to refuse treatment*, and pragmatically because forced vaccination will deter at least some people from seeking medical help when they need it."
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> "Following this flawed logic, several state-based proposals have sought to address any 'public health emergency,' … [by] resort[ing] to *punitive, police-state tactics*, such as forced examinations, *vaccination* and treatment, and criminal sanctions for those individuals who did not follow the rules."
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> -The American Civil Liberties Union in 2008
> (before it became the Anti-Civil Liberties Union)

The Cuomo Administration and the "Public Health Emergency" Come to an End

14. On August 23, 2021, the People of the State of New York were definitively rescued from the nearly eighteen-month-long medical dictatorship of ex-Governor Cuomo, who resigned in disgrace and forfeited the Emmy Award for his press conference "performances" as the savior of New York from the coronavirus.[1]

15. The legacy of Cuomo's medical dictatorship was the second highest COVID death rate per 100,000 in the country—with New Jersey in first place under the equally draconian and

[1] *See* Nick Niedzwiaek, "Cuomo Loses Emmy following scandal, resignation," POLITICO, August 24, 2021, https://www.politico.com/states/new-york/albany/story/2021/08/24/cuomo-loses-emmy-following-scandal-resignation-1390423

still-ongoing medical dictatorship of Governor Murphy.[2] There is an ongoing FBI investigation into official concealment of the 15,000 COVID deaths caused by Cuomo's order to return COVID-positive patients to nursing homes after their discharge from the hospital.[3]

16. On June 25, 2021, two months before his last day in office, Cuomo finally rescinded his declaration of a "State disaster emergency"—fifteen months after it was issued—along with all the executive orders that followed. There is no longer a public health emergency in the State of New York. Despite the incessant media fearmongering over the "Delta variant" and now the "Mu variant," on September 7, 2021, only 47 deaths out of a state population of almost 20,000,000 could be attributed (however loosely) to the virus.[4]

The Vaccination Mandate
Supersedes the Prior Health Order

17. The end of the Cuomo administration, however, has apparently not been accompanied by any institutional awareness of the failure of his policies to improve the lot of New Yorkers during the pandemic as compared to virtually every other State in the Union. On the contrary, the defendant Health Commissioner, Howard A. Zucker, and Cuomo's successor as Governor, defendant Governor Kathy Hochul (Hochul), continue to behave as if the "disaster emergency" had never ended—and never will end.

18. Solely on the pretext of what the DOH's Public Health and Health Planning Council ("the Health Council") deems "a concerning national trend of increasing circulation of the SARS-CoV-2 Delta variant," Zucker and the DOH, with the assistance of defendant

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[2] *See* https://www.statista.com/statistics/1109011/coronavirus-covid19-death-rates-us-by-state/. New York was only recently bumped to third worst in the nation, but only barely, by Mississippi.
[3] *See* Michael Gold and Ed Shanahan, "What We Know About Cuomo's Nursing Home Scandal," August 4, 2021, https://www.nytimes.com/article/andrew-cuomo-nursing-home-deaths.html
[4] *See* https://www.worldometers.info/coronavirus/usa/new-york/

Attorney General Letitia James and the approval of Hochul as the State's chief executive, are now enforcing the Health Council's proposed COVID-19 "emergency" regulation, the aforesaid Vaccine Mandate, effective only days ago, on August 26, 2021.

19. The Vaccine Mandate orders the COVID-19 vaccination of the "personnel" of all "covered entities" in the field of medical and health services, including the Plaintiffs and all the hospitals, clinics, or private practices with which they are associated. *See* Exhibit A to this Complaint and NYCRR, Title 10, Part 2, § 2.61 ("the Vaccine Mandate").

20. The Vaccine Mandate excludes any religious exemption from COVID-19 vaccination but permits medical exemptions. Yet, only days before, the superseded Public Health Order issued in the waning days of the Cuomo administration (the "prior Health Order")—one of the few things he got right—provided a broad and indeed constitutionally required religious exemption:

> Religious exemption. Covered entities *shall grant a religious exemption* for COVID-19 vaccination for covered personnel if they hold a genuine and sincere religious belief contrary to the practice of immunization, subject to a reasonable accommodation by the employer. Covered entities shall document such exemptions and such reasonable accommodations in personnel records or other appropriate records in accordance with applicable privacy laws by September 27, 2021, and continuously, as needed, thereafter.

See Exhibit B to this Complaint (emphasis added)

21. The Vaccination Mandate declares that "Covered entities shall *continuously* require personnel to be fully vaccinated against COVID-19, with the first dose for current personnel received by September 27, 2021 for general hospitals and nursing homes, and by October 7, 2021 for other covered entities absent receipt of an exemption." Mandate at 2.61 (c) (emphasis added).

22. Ominously enough, by "continuously… fully vaccinated" the Vaccine Mandate

appears to contemplate however many "booster shots" of COVID vaccine federal and state health bureaucrats demand: "'Fully vaccinated,' for the purposes of this section, shall be determined by the Department in accordance with applicable federal guidelines and recommendations." Id. at § 3.

23. In the State of Israel, where COVID vaccines are already failing massively to "contain the virus," the national government has announced that "fully vaccinated" now means *three* shots.[5] Or perhaps *four* shots very soon, as Israel's top health expert suggests.[6] In this country, the Biden administration is already promoting the three shots = "fully vaccinated" narrative: "It will make you safer, and for longer, and it will help us end the pandemic faster," said Biden said in a speech on August 18.[7]

24. As pleaded more particularly below, the Vaccine Mandate purports to override federal protections under Title VII, commanding employers to deny religious accommodation of sincere religious objections to vaccination—a blatant violation of the Supremacy Clause as well as the Free Exercise Clause. The Vaccine Mandate even nullifies parallel state law protections under the New York Human Rights Law and the New York City Human Rights Law.

25. Only days after the prior Health Order had declared "Covered entities *shall* grant a religious exemption" in recognition of federal and state law, the Vaccine Mandate effectively declared that "covered entitles" *shall not* grant a religious exemption. The targeting of a large

[5] "Three doses not two: Israel sets new benchmark for full vaccination. It is on India's horizon as well," *The Times of India*, September 1, 2021 @ https://timesofindia.indiatimes.com/blogs/toi-editorials/three-doses-not-two-israel-sets-new-benchmark-for-full-vaccination-it-is-on-indias-horizon-as-well/

[6] "New normal: Israel's health expert says fourth shot of Covid vaccine needed," September 5, 2021, Wio News, https://www.wionews.com/world/new-normal-israels-health-expert-says-fourth-shot-of-covid-vaccine-needed-410904

[7] https://www.politico.com/news/2021/08/18/biden-recommends-covid-booster-shots-505911

class of religious objectors to mandatory vaccination among health professionals, who are very knowledgeable on this subject—and notably at least 20% of the health care workforce in New York[8]—is plainly evident. Yet any ill-informed college student can obtain a religious exemption from a panoply of vaccinations simply by filing a statement that "he/she objects to immunization due to his/her religious beliefs." *See* Public Health Law § 2165.

Reasons for Proceeding with Pseudonyms

26. The same "front line" health care workers hailed as heroes by the media for treating COVID patients before vaccines were available, including the Plaintiffs herein, are now vilified by the same media as pariahs who must be excluded from society until they are vaccinated against their will.

27. The Vaccine Mandate emerges in the context of an atmosphere of fear and irrationality in which the unvaccinated are threatened with being reduced to a caste of untouchables if they will not consent to being injected, even "continuously," with vaccines that violate their religious beliefs, are clearly not as effective as promised, and have known and increasingly evident risks of severe and even life-threatening side effects, including blood clots[9] and what the CDC admits is "a 'likely association' between a rare heart inflammatory condition in adolescents and young adults [under age 30] mostly after they've received their second Covid-19 vaccine shot…"[10]

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[8] *See* letter to defendants Zucker and Hochul from numerous members of the State Assembly @ https://www.scribd.com/document/523955400/COVID-Vaccination-Letter#from_embed

[9] Cf. authoritative study in the prestigious journal *Nature*: "Antibody epitopes in vaccine-induced immune thrombotic thrombocytopaenia," July 7, 2021; available at https://www.nature.com/articles/s41586-021-03744-4

[10] *See* Berkeley Lovelace, Jr. "CDC safety group says there's a likely link between rare heart inflammation in young people after Covid shot," CNBC, June 23, 2021 @ https://tinyurl.com/sse5zsr9

28. With caution thrown to the winds, everyone—the young and healthy, the old, the previously recovered and naturally immune, even pregnant and breastfeeding women—is now being pressured by governments, businesses and educational institutions to submit to COVID-19 vaccination with no assessment of the risks or benefits for each individual or any consideration of medical necessity or contraindication in each particular case. Even the smallest children, at virtually no risk from the virus, are to be vaccinated as soon as a rushed approval can be obtained from the FDA.

29. For the sake of forcing people to be inoculated with novel vaccines regardless of risk or benefit, college admissions are being revoked, career paths blocked, employment terminated, and lives ruined on a vast scale. Nothing like this has ever been seen in our nation.

30. And yet the CDC now admits that the COVID vaccines do not prevent viral transmission or infection, especially by the "Delta variant."[11]

31. As things now stand, according to "public health authorities" the vaccinated can infect the unvaccinated, the unvaccinated can infect the vaccinated, both the vaccinated and the unvaccinated can infect each other, and everyone must wear masks indoors in "high transmission" areas—that is, virtually the entire country[12]—as if no one at all had been vaccinated.[13] And with both the "fully vaccinated" and the unvaccinated still contracting COVID, "continuous" "booster shots" of the same less-than-miraculous vaccines, to which

[11]Frank Diamond, *Infection Control Today*, "Vaccines Not as Effective against the Delta Variant, say CDC Data," August 25, 2021 @ https://www.infectioncontroltoday.com/view/vaccines-not-as-effective-against-delta-variant-says-cdc-data

[12]*See* CDC Map at https://www.usatoday.com/in-depth/graphics/2021/07/29/cdc-mask-guidelines-map-high-covid-transmission-county/5400268001/

[13]*See* "When You've Been Fully Vaccinated," https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html

plaintiffs have the same religious objections, are doubtless on the way, accompanied by further government mandates.

32. In the midst of this regulatory muddle, combined with unreasoning official coercion and widespread, media-generated panic, plaintiffs seek leave of court to proceed anonymously as they run the risk of ostracization, threats of harm, immediate firing and other retaliatory consequences if their names become known. This is shown by the following examples of a pervasive climate of fear and loathing of the unvaccinated:

- MSNBC guest Frank Schaeffer stating that those who are "anti-vaccine" are "bio terrorists" who should be the target of "Drone strikes."[14]

- In the Eastern District of New York, where two of the Plaintiffs reside, an explicit death threat was made in a comment that had to be deleted (likely for fear of liability on the part of the publishers) (Exhibit C)[15]

- Mayor de Blasio, announcing his "vaccine passport" for New York City, which affects several of the plaintiffs herein, declared that "If you want to participate in our society fully, you've got to get vaccinated."[16]

- On ABC News, commentator Margaret Hoover declared that government, by withholding all benefits from the unvaccinated, should "just make it almost impossible for people to—to live their lives without being protected and protecting the rest of us."[17]

- On CNN, commentator Don Lemon stated to Chris Cuomo that "[If ou] don't get the vaccine, you can't go to the supermarket. Don't have the vaccine, can't go to the ball game. Don't have a vaccine, can't go to work. You don't have a vaccine, can't come here. No shirt, no shoes, no service."[18]

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[14] https://www.breitbart.com/politics/2021/09/10/msnbc-guest-calls-drone-strikes-americans-opposed-vaccine-mandates/

[15] https://riverheadlocal.com/2021/09/04/protest-outside-riverhead-hospital-draws-crowd-of-vaccine-mandate-opponents/

[16] *See* video @ https://tinyurl.com/j4npw5c h

[17] This Week," July 25, 2021, https://abcnews.go.com/Politics/week-transcript-25-21-speaker-nancy-pelosi-sen/story?id=79045738

[18] https://www.realclearpolitics.com/video/2021/08/01/don_lemon_no_shirt_no_shoes_no_vaccine_no_service.html

- On his late night "comedy" show Jimmy Kimmel stated that the unvaccinated who contract COVID should be allowed to die rather than being admitted to the hospital: "Rest in peace, wheezy."[19] The audience roared its approval. Kimmel offered no such advice to the millions who seek emergency medical treatment after disregarding constant public health warnings against smoking, drinking, drug abuse, and junk food-induced Type II diabetes.

- In *The Week*, Ryan Cooper declared that "Anti-vaxxers" (i.e. people who decline the COVID vaccines) "should be exiled from society until they get their shots, and their efforts to intimidate people against controlling the pandemic should be met with massive resistance."[20]

33. Furthermore, plaintiffs' allegations below involve sensitive personal medical information concerning their vaccination status, the presence of antibodies, and whether they are breastfeeding or intending to become pregnant.

34. Under these circumstances, plaintiffs clearly meet the criteria for permission to proceed anonymously. *See* Memorandum of Law in Support of this application.

Plaintiffs' Common Religious Beliefs Opposing Compulsory COVID-19 Vaccination

35. The following allegations detail plaintiffs' sincere religious conviction that they cannot consent to be inoculated, "continuously" or otherwise, with vaccines that were tested, developed or produced with fetal cells line derived from procured abortions, and the drastic consequences they now face absent emergency injunctive relief.

36. The seventeen plaintiffs in this action—practicing doctors, M.D.s fulfilling their residency requirement, nurses, a nuclear medicine technologist, a cognitive rehabilitation therapist and a physician's liaison—are united in their conscientious religious objection as Christians to being inoculated at all, much less "continuously," with any of the available

[19] https://www.westernjournal.com/late-night-host-ghoulishly-mocks-sick-unvaccinated-rest-peace-wheezy/

[20] https://theweek.com/coronavirus/1002909/theres-1-obvious-solution-to-the-delta-variant-mandatory-vaccination

COVID-19 vaccines because they all employ fetal cell lines derived from procured abortion in testing, development or production of the vaccines. In particular:

- Johnson & Johnson/Janssen: Fetal cell cultures are used to produce and manufacture the J&J COVID-19 vaccine and the final formulation of this vaccine includes residual amounts of the fetal host cell proteins (≤0.15 mcg) and/or host cell DNA (≤3 ng).

- Pfizer/BioNTech: The HEK-293 abortion-related cell line was used in research related to the development of the Pfizer COVID-19 vaccine.

- Moderna/NIAID: Aborted fetal cell lines were used in both the development and testing of Moderna's COVID-19 vaccine.

37. Plaintiffs hold in common the following sincere religious beliefs concerning abortion-connected vaccines:

a) They oppose abortion under any circumstances, as they believe that abortion is the intrinsically evil killing of an innocent, and thus they also oppose the use of abortion-derived fetal cell lines for medical purposes and abortion-derived fetal stem cell research.

b) It would be a violation of their deeply held religious beliefs and moral consciences to take any of the available COVID-19 vaccines given their use of abortion-derived fetal cell lines in testing, development, or production.

c) By receiving one of the COVID vaccines currently available, all of which are abortion-connected, they believe they would be cooperating with the evil of abortion in a manner that violates their consciences and that they would sin gravely if they acted against their consciences by taking any of these vaccines.

d) They agree with the teaching of spiritual leaders, including certain Catholic bishops, who urge Christians to refuse said vaccines to avoid cooperation in

abortion and to bear witness against it without compromise, and who defend the right to a religious exemption from vaccination with such vaccines.

e) They do not accept the opinion—expressed by certain other Catholic bishops, the Pope included—that there is a therapeutically proportional reason to resort to abortion-connected vaccines which can justify "remote" cooperation in abortion. They reject as a matter of religious conviction *any* medical cooperation in abortion, no matter how "remote."[21]

f) They believe in the primacy of conscience in this matter. While one may personally conclude that recourse to abortion-connected vaccines can be justified in his or her case, vaccination is not morally obligatory and *must* be voluntary, and those who in conscience refuse vaccination need only take other protective measures to avoid spreading the virus.[22]

g) Although they are not "anti-vaxxers" who oppose all vaccines, they believe as a matter of religious conviction that the ensouled human person, made in the image and likeness of God, is inviolable as a temple of the Holy Ghost and that civil authorities have no right to *force* anyone to be medicated or vaccinated against his or her will, whether or not the medication or vaccine is abortion-connected.

[21]*See*, Exhibit D (collecting statements of Catholic prelates, who call for conscientious abstention from abortion-connected vaccines).

[22]*See*, "Note on the Morality of Using Some Anti-COVID-19 Vaccines," https://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20201221_nota-vaccini-anticovid_en.html

h) A risk-benefit analysis factors into each person's formulation of a conscientious religious position on the morality of vaccinations.[23] Plaintiffs are all aware of the vaccines' side effects, which can be quite serious, their fading efficacy, requiring "booster shots," their evident inability to prevent transmission or infection, (*see* Exhibit F)[24] and the fact that natural immunity is likely more protective than injections with the available COVID-19 vaccines.[25] These medical facts inform Plaintiffs' religious conviction against involuntary or coerced vaccination as an invasion of bodily autonomy contrary to their religious beliefs. Given that the Vaccine Mandate requires that employers insure that employees are "continuously" "fully vaccinated"—as many times as the government advises—Plaintiffs now reasonably fear that "booster shots" of the same vaccines they consider immoral will soon be demanded by the government as a condition of employment and even normal life in society, as is already the case with the original vaccines.

Plaintiff "Dr. A."

38. Plaintiff A., M.D. ("Dr. A."), who is Catholic, is a board-certified Anatomic and Clinical Pathologist on staff at a private hospital in the Northern District, where he performs pathology testing and diagnosis under contract with the hospital.

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[23]*See*, "A Letter from the Colorado Bishops on COVID-19 Vaccine Mandates," August 5, 2021 @ https://cocatholicconference.org/a-letter-from-the-bishops-on-covid-19-vaccine-mandates/

[24] On August 5, 2021, during a CNN interview, CDC Director Rochelle Walensky stated that because of the new spread of the delta variant, "what [the COVID vaccines] can't do anymore is *prevent transmission*," (emphasis added), http://www.cnn.com/TRANSCRIPTS/2108/05/sitroom.02.html; *see also* Exhibit F (reproducing transcript of this interview).

[25]*See*, Exhibit E (on the science pertaining to natural versus vaccine-induced immunity).

39. On August 12, 2021, Dr. A., who seeks a religious exemption from COVID vaccination based on the religious beliefs enumerated in ¶ 37 (a)-(h), was informed by the hospital administration via email that the hospital would be mandating the Covid-19 vaccination for all employees and medical staff members who provide on-site care. Unvaccinated staff members could refuse the vaccine without penalty but would be required to undergo weekly testing.

40. This policy changed on or about August 20, 2021, due to the DOH's issuance of the prior Health Order, which eliminated testing in lieu of vaccination but did allow both medical and religious exemptions.

41. On August 27, 2021, however, the hospital policy changed again after DOH issued the Vaccinate Mandate removing the religious exemption provision under the prior Health Order.

42. Knowing that religious exemptions had been banned by the DOH, on August 31, 2021, Dr. A. sent the hospital administration the required form for a medical exemption instead, but has not yet received a reply.

43. Refusal to receive an abortion-connected COVID-19 vaccine will imminently result in the loss of Dr. A's position at the hospital and this termination of employment would have to be mentioned in Dr. A.'s license renewal statements, which could trigger disciplinary proceedings against him.

44. Dr. A. is now also at risk of disciplinary charges by the DOH or otherwise that could result in loss of his license if he refuses, as he must, vaccination with any of the currently available abortion-connected vaccines. There is also the threat that the DOH will make COVID-

19 vaccination a condition of renewal or threaten license suspension or revocation in order further to coerce Dr. A. to be vaccinated with a vaccine he cannot take in good conscience.

45. The imminent loss of his position and staff privileges at the hospital with which Dr. A. is affiliated will make it impossible to conduct his practice and will also render him unemployable anywhere in the State of New York as no other hospital would place him on the pathology staff under the Vaccine Mandate.

46. Dr. A. will suffer imminent irreparable harm to his occupation, reputation, and professional standing in the absence of injunctive relief barring enforcement of the Vaccine Mandate.

Plaintiff "Nurse A."

47. Plaintiff A., R.N. ("Nurse A."), who is Catholic, is a registered nurse, licensed in the State of New York, who works in a major medical center in the Southern District.

48. Nurse A. has cared for numerous dialysis patients with COVID during the pandemic without need of vaccination.

49. On August 20, 2021, Nurse A. received a religious exemption from COVID vaccination from her hospital, based on the religious beliefs enumerated in ¶ 37 (a)-(h),On August 30, 2021, however, Nurse A. received an email revoking her religious exemption because of the Vaccine Mandate, which email stated that her hospital "must follow NYS DOH requirements as they evolve. This means that [the hospital] can no longer consider any religious exemptions to the COVID vaccination *even those previously approved*."

50. Said email further warned that "employees who do not comply with the vaccination program by the deadlines above will be placed off duty for seven days without pay, and given

those seven days to meet the program requirements. Employees who choose not to meet the program requirements after seven days will be deemed to have opted to resign."

51. Nurse A. has been given a deadline of September 15, 2021 to receive the "first dose" of COVID vaccine.

52. Termination of Nurse A.'s employment will be devastating to her and her family. Nurse A. will also be unemployable anywhere in the State of New York as no other hospital would hire her under the Vaccine Mandate.

53. Nurse A.'s termination will have to be reported at the time of license renewal and may well trigger disciplinary proceedings against her. There is also the threat that the DOH will make COVID-19 vaccination a condition of her license renewal to further coerce compliance.

54. Nurse A. is now also under the threat of disciplinary proceedings by the DOH, including license suspension or revocation as measure of coercion to take a vaccine that in her informed medical judgment she cannot take in good conscience.

55. Nurse A. will suffer imminent irreparable harm to her occupation, reputation, and professional standing in the absence of injunctive relief barring enforcement of the Vaccine Mandate.

Plaintiff "Dr. C."

56. Plaintiff C, M.D. ("Dr. C."), who is Catholic, is a board-certified ophthalmologist who is an attending physician with admitting privileges at a private hospital in the Northern District, and he also directs a large private surgical practice.

57. During 2020, Dr. C.'s large practice group performed almost 10,000 surgeries without a single case or outbreak of COVID-19 traceable to his practice and without vaccination of anyone on staff.

58. Prior to the Vaccine Mandate, religious exemption and periodic testing in lieu of vaccination were allowed under the prior Health Order that the Vaccine Mandate superseded, as to which exemption Plaintiff Dr. C. was in discussions with hospital management.

59. Plaintiff Dr. C. has now been advised by said hospital that on account of the Vaccine Mandate he must be COVID-vaccinated by September 27, 2021, and that there is no religious exemption.

60. Dr. C.'s written request for an exemption, reflecting the religious beliefs enumerated in ¶ 37 (a)-(h), was thus denied on September 1, the same day it was submitted.

61. The imminent loss of admitting privileges at the hospital with which Dr. C is affiliated will make it impossible to conduct his practice, as he cannot conduct ophthalmic and maxillofacial surgery without the ability to admit patients to a hospital if the need arises.

62. The imminent loss of privileges will also render Dr. C. unemployable anywhere in the State of New York as no other hospital would grant him privileges under the Vaccine Mandate.

63. The imminent loss of privileges will have to be reported at the time of license renewal and may well trigger disciplinary proceedings against Dr. C. There is also the threat that the DOH will make COVID-19 vaccination a condition of license renewal in a further bid to coerce compliance.

64. Dr. C. is now also under the threat of disciplinary proceedings by the DOH, including license suspension or revocation, for refusing to obey the Vaccine Mandate by taking a vaccine that in his informed medical judgment he cannot take in good conscience.

65. Dr. C. will suffer imminent irreparable harm to his occupation, reputation, and professional standing in the absence of injunctive relief barring enforcement of the Vaccine Mandate.

Plaintiff "Nurse D."

66. Plaintiff D., R.N. ("Nurse D."), who is Catholic, is a registered nurse, licensed in the State of New York, who works at a private hospital in the Northern District. She has two sons and a husband, and her job is a vital source income and health and dental insurance for her family.

67. Nurse D. attempted to obtain a religious exemption from her hospital, based on the religious beliefs enumerated in ¶ 37 (a)-(h), but it was denied on account of the Vaccine Mandate. She has been advised by management that if she is not vaccinated by September 27, she will be deemed to have "voluntarily resigned."

68. In a memo issued September 7, 2021, management further advised that the employment of Nurse D. and any other employee refusing vaccination under the Vaccine Mandate will end on September 28, the separation will be "deemed" to be voluntary, meaning no unemployment benefits, and all health and other benefits will terminate.

69. Termination of Nurse D's employment will be devastating to her and her family. Nurse D. has more than $50,000 of student loans from her nursing program alone.

70. Nurse D. will also be unemployable anywhere in the State of New York as no other hospital would hire her under the Vaccine Mandate.

71. Nurse D.'s termination will have to be reported at the time of license renewal and may well trigger disciplinary proceedings against her. There is also the threat that the DOH will make COVID-19 vaccination a condition of her license renewal to further coerce compliance.

72. Nurse D. is now also under the threat of disciplinary proceedings by the DOH, including license suspension or revocation as measure of coercion to take a vaccine that in her informed medical judgment she cannot take in good conscience.

73. Nurse D. will suffer imminent irreparable harm to her occupation, reputation, and professional standing in the absence of injunctive relief barring enforcement of the Vaccine Mandate.

Plaintiff "Dr. F."

74. Plaintiff F., D.D.S., M.D. ("Doctor F."), who is Catholic, is a board-certified Oral and Maxillofacial Surgeon, licensed in dentistry and medicine in the State of New York.

75. Dr. F. is employed by a private hospital in the Northern District, where he is on staff and has admitting privileges in addition to his private practice.

76. Dr. F. and his partners have treated numerous patients who were sick with COVID without need of vaccination. Patients with COVID were not turned away but received dental treatment that was urgently needed. Dr. F.'s clinic is vital to the region in which it is located and cannot turn away patients in need of urgent care.

77. Although he was granted a religious exemption from COVID vaccination under the prior Health Order, the Vaccine Mandate has forced his hospital employer to revoke it and he was notified by hospital administration that if he fails to provide proof of vaccination by September 21, 2021, his hospital privileges will be suspended.

78. In addition to the concerns about the scientific questions pertaining to the available COVID-19 vaccines noted in ¶ 37(h), Dr. F. also knows of two people who have died, one who had a heart attack, and many others who have been injured following injection with a COVID

vaccine. These medical facts inform Dr. F's religious objection to involuntary vaccination of any kind, including COVID vaccines, although he is not "anti-vax" in general.

79. The imminent loss of admitting privileges at the hospital with which Dr. F is affiliated will make it impossible to conduct his practice, as he cannot conduct oral and maxillofacial surgery without the ability to admit patients to a hospital if the need arises.

80. The imminent loss of privileges will also render Dr. F. unemployable anywhere in the State of New York as no other hospital would grant him privileges under the Vaccine Mandate, which he cannot in conscience obey.

81. The imminent loss of privileges will have to be reported at the time of license renewal and may well trigger disciplinary proceedings against Dr. F. There is also the threat that the DOH will make COVID-19 vaccination a condition of license renewal in a further bid to coerce compliance with the Vaccine Mandate.

82. Dr. F. is now also under the threat of disciplinary proceedings by the DOH, including license suspension or revocation—yet another measure of coercion to take a vaccine that in his informed medical judgment he cannot take in good conscience.

83. Dr. F. will suffer imminent irreparable harm to his occupation, reputation, and professional standing in the absence of injunctive relief barring enforcement of the Vaccine Mandate.

Plaintiff Dr. "G."

84. Plaintiff G., M.D. ("Dr. G."), who is Catholic, is a board-certified specialist in Internal Medicine, licensed in the State of New York, who is employed by two private hospitals operated by a health service in the Western District at which he has staff and admitting

privileges. Dr. G also directs an internal medicine residency program in which he instructs dozens of M.D.s who are fulfilling their residency requirements.

85. Dr. G., who seeks a religious exemption from COVID vaccination based on the beliefs enumerated in ¶ 37 (a)-(h), has been informed by the Medical Affairs Department that there is no religious exemption from the Vaccine Mandate and that if he is not "fully vaccinated" by September 27 he will not be allowed to enter any of the buildings of the health service, including the hospitals in which he works and teaches.

86. The imminent loss of Dr. G.'s positions and admitting privileges at the hospitals with which he is affiliated will make it impossible for him to conduct his practice.

87. The imminent loss of his positions and privileges will also render Dr. G. unemployable anywhere in the State of New York as no other hospital would grant him privileges under the Vaccine Mandate, which he cannot in conscience obey.

88. The imminent loss of privileges and the termination of his employments will have to be reported at the time of license renewal and may well trigger disciplinary proceedings against Dr. G. There is also the threat that the DOH will make COVID-19 vaccination a condition of his license renewal.

89. Dr. G. is now also under the threat of disciplinary proceedings by the DOH, including license suspension or revocation as a further measure of coercion to take a vaccine that in his informed medical judgment he cannot take in good conscience.

90. Dr. G. will suffer imminent irreparable harm to his occupation, reputation, and professional standing in the absence of injunctive relief barring enforcement of the Vaccine Mandate.

Plaintiff "Therapist I."

91. Plaintiff I. ("Therapist I."), who is Catholic, is a certified brain injury specialist who provides cognitive rehabilitation and other assistance to patients, groups of patients, their families and visitors at a facility located in the Northern District.

92. In October of 2020, Therapist I. treated COVID patients as a TNA (temporary nurses' aide) on a dedicated COVID Unit in a nursing home. Therapist I. was part of a team that the parent facility set up to travel among its properties when the destination facility was in a staffing crisis. Therapist I. did not require any form of vaccination to treat these patients but rather was tested twice a week.

93. Therapist I. knows of two colleagues who were "fully vaccinated" yet still contracted COVID-19 and had to be quarantined. These medical facts, along with those recited herein above, inform Therapist I's religious objection to involuntary vaccination as a violation of human dignity.

94. Therapist I., who seeks a religious exemption from COVID vaccination based on the beliefs noted in ¶ 37 (a)-(h), has been advised by his employer, a rehabilitation center, that, because of the Vaccine Mandate, he must receive "at least the first dose" of an abortion-connected vaccine by September 27, 2021.

95. Therapist I. is now facing imminent termination of his employment and damage to his reputation and future employment prospects if he refuses to be vaccinated against his religious belief.

96. Therapist I. is also at risk of action against his certification in EMS as the DOH imposing the Vaccine Mandate also regulates the granting, oversight and renewal of his EMT-B certificate.

97. Therapist I will thus suffer imminent irreparable harm to his occupation, reputation, and professional standing in the absence of injunctive relief barring enforcement of the Vaccine Mandate.

Plaintiff "Doctor J."

98. Plaintiff J., D.O., who is Catholic, is a Doctor of Osteopathy ("Dr. J."), licensed in the State of New York, whose specialty is Obstetrics and Gynecology, for which she is board-certified. She has admitting privileges at a private hospital in the Western District in addition to her private practice.

99. Dr. J. believes she has probably treated dozens of women with COVID, most of whom were asymptomatic, and may have had an asymptomatic case of COVID herself. She works in Labor and Delivery two days per week, training residents, and cares for "unassigned patients" who don't have a doctor. All patients are tested for COVID. Sometimes if the delivery was happening quickly, Dr. J. would have to run into the room without knowing the patient's COVID status, and there was not always time to wear proper personal protection equipment (PPE). She would find out after the fact that the patient was COVID-positive. Dr. J. has had 5 to 8 patients who were admitted specifically due to complications of COVID in pregnancy. She assisted in their treatment even while she herself was pregnant.

100. As an OBGYN, Dr. J. has always practiced in accord with the dictates of her personal religious convictions, including the beliefs enumerated above, and she does not perform any form of abortion or sterilization procedure, nor prescribe any contraceptive that could induce an unintentional abortion.

101. Dr. J. is currently breastfeeding her daughter, is aware of reports of the death of breastfeeding infants following maternal vaccination, and is not aware of any studies to date that

would prove safety in breastfeeding or during pregnancy, which is of particular concern to her as an OB-GYN. Her hospital's own notice of the Vaccination Mandate advises breastfeeding women hesitantly as follows: "Evidence about the safety and effectiveness of COVID-19 vaccination during pregnancy is growing… It's best to talk to your OB-GYN or pediatrician about any questions or concerns you have."

These medical facts, along with those recited herein above, inform Dr. J.'s religious conviction against involuntary vaccination as an invasion of bodily autonomy that is contrary to Catholic Church teaching, especially in the case of COVID vaccination while she is breast-feeding or pregnant, when the welfare of her child is also implicated.

102. Dr. J., who seeks a religious exemption from COVID vaccination that reflects the beliefs set forth in ¶ 37 (a)-(h), has been advised by hospital management that unless she has the "first shot" of COVID vaccine by September 27, she can no longer have admitting privileges at the hospital.

103. Refusal to receive an abortion-connected COVID-19 vaccine will imminently result in the loss of Dr. J.'s admitting privileges, which will make it impossible to conduct her practice.

104. The loss of privileges due to refusal to comply with the Vaccine Mandate would have to be mentioned in her license renewal statements, which could trigger disciplinary proceedings against Dr. J.

105. There is also the threat that the DOH will make COVID-19 vaccination a condition of renewal or threaten license suspension or revocation in order further to coerce Dr. J. to be vaccinated with a vaccine she does not need in her informed medical judgment, does not want, and cannot take in good conscience.

106. The loss of admitting privileges at the hospital with which Dr. J. is affiliated will also render her unemployable anywhere in the State of New York as no other hospital would grant her admitting privileges under the Vaccine Mandate.

107. Dr. J. will suffer imminent irreparable harm to her occupation, reputation, and professional standing in the absence of injunctive relief barring enforcement of the Vaccine Mandate.

Plaintiff "Nurse J."

108. Plaintiff J., L.P.N. ("Nurse J."), who is Baptist, is a licensed practical nurse, licensed in the State of New York, who provides home nursing care for two private home care agencies doing business in the Eastern District.

109. Nurse J. has cared for COVID patients on an in-home basis, including a patient who had to be hospitalized for several months, on which occasion Nurse J had to be quarantined for two weeks. Nurse J. developed COVID-like symptoms and believes she has had the virus and thus has acquired natural immunity.

110. While not a Catholic, Nurse J. shares the common beliefs of the plaintiffs, as enumerated above.

111. On September 6, 2021, Nurse J. sent a letter of protest concerning the Vaccine Mandate to the administration of the agencies for which she works, urging them not to capitulate to the State. But on September 7, 2021, Nurse J. was advised by management that there would be no religious exemptions from vaccination, "much to our disappointment."

112. Nurse J. has requested a religious exemption but does not expect to receive one, given the Vaccine Mandate. On September 9, 2021, Nurse J. was advised by the executive

director of one of the agencies that employ her that no religious exemption is possible due to the Vaccine Mandate and that "my hands are tied."

113. Nurse J. is now facing imminent termination of her employment as of October 7, 2021, the compliance date for entities other than hospitals and nursing homes under the Vaccine Mandate. She will also be unemployable anywhere in the State of New York as no other hospital would hire her under the Vaccine Mandate.

114. Nurse J.'s termination will have to be reported at the time of license renewal and may well trigger disciplinary proceedings against her. There is also the threat that the DOH will make COVID-19 vaccination a condition of her license renewal.

115. Nurse J. is now also under the threat of disciplinary proceedings by the DOH, including license suspension or revocation as a further measure of coercion to take a vaccine that in her informed medical judgment she cannot take in good conscience.

116. Nurse J. will suffer imminent irreparable harm to her occupation, reputation, and professional standing in the absence of injunctive relief barring enforcement of the Vaccine Mandate.

Plaintiff "Dr. M."

117. Plaintiff M., M.D. ("Dr. M"), who is Catholic, is a medical school graduate in the process of completing her residency at a private hospital in the Western District.

118. On August 19, 2021, during the short time the prior Health Order was in effect, Dr. M. received an email from Human Resources advising that all residents must be vaccinated for COVID-19 and that "Information regarding waivers for medical or religious reasons will be available shortly."

119. On August 25, 2021, however, Dr. M. received an email from administration warning that "disregarding the NYS Vaccination Mandate may affect your ability to continue working and training with your residency or fellowship program." There was no indication of an allowance for religious exemptions.

120. On August 30, 2021, Dr. M. received another email from HR advising that "Late last week, the NYS Public Health & Planning Council and the NYS Commissioner of Health *removed the religious exemption* for the recent state mandate requiring all health professionals get vaccinated for COVID-19." Dr. M. was thus barred from obtaining the religious exemption from COVID vaccination that she seeks, based on the religious beliefs enumerated above.

121. In addition to the medical concerns recited in ¶37 (h), Dr. M. has personally witnessed a medical student having a seizure after receiving the one-shot Johnson & Johnson vaccine. She collapsed to the floor and a rapid response team was summoned because she was unresponsive. She recovered with the assistance of the team. These medical facts inform Dr. M.'s religious conviction against involuntary vaccination.

122. On September 3, 2021, the hospital administration further advised Dr. M. by email that she must receive the "first dose" of a COVID vaccine by September 27 and that "Disregarding the NYS Vaccination Mandate may affect your ability to continue working and training with your residency or fellowship program."

123. Dr. M. has met with her program director to discuss her religious objection to COVID vaccination, but was met only with reiteration of the warning that her residency was at risk if she did not accept vaccination.

124. Dr. M. now faces the imminent loss of her residency and thus the destruction of her entire career as she can never become a fully licensed physician and practice independently without completing a residency.

125. Given the Vaccine Mandate, Dr. M. will be unable to find a residency anywhere in the State of New York due to her conscientious religious abstention from vaccination.

126. Further, termination of her residency for refusal to obey the Vaccine Mandate in violation of her religious belief is likely to have adverse consequences for Dr. M.'s licensure in New York or any other jurisdiction.

127. Dr. M. will suffer imminent irreparable harm to her occupation, reputation, and professional standing in the absence of injunctive relief barring enforcement of the Vaccine Mandate.

Plaintiff "Nurse N."

128. Plaintiff N., B.S.N, R.N.-C.("Nurse N.), who is Catholic, is a Bachelor's-prepared, medical-surgical certified Registered Nurse, licensed in the State of New York, who works at a hospital in the Northern District.

129. On August 19, 2021, Nurse N., under the prior regime that included the Health Order, received an exemption from COVID vaccination on the basis of anticipated pregnancy and current breastfeeding, and thus did not submit an additional request to her employer for religious exemption, which she would have done, based on the beliefs enumerated above, had her request for exemption related to pregnancy and breastfeeding been denied. Nurse N.'s request for exemption was approved as a "vaccination deferral."

130. On September 1, 2021, however, Nurse N. was notified by hospital administration that the Vaccine Mandate had eliminated all exemptions for religion and pregnancy, that her

exemption was thus revoked, and that she must receive at least one dose of a COVID-19 vaccine by September 21.

131. Nurse N. does not accept the view that recourse to abortion-connected vaccines can be justified as "remote" cooperation in abortion. She rejects any medical cooperation in abortion, "remote" or otherwise.

132. Nurse N. also believes and follows the religious teaching of the Congregation for the Doctrine of the Faith that vaccination is not morally obligatory. Nurse N. does not oppose vaccination generally, and is not an "anti-vaxxer," but does oppose government imposition of any medication or vaccine without informed consent, which she views with sincere religious conviction as a violation of the dignity of the human person.

133. Further, Nurse N. has had COVID-19, from which she recovered. As a medical professional who has read the pertinent medical literature, Nurse N. knows that she has natural immunity that is superior to the vaccine-induced immunity that is already fading, that she is in no need of vaccination by any form of COVID vaccine, and that all available COVID vaccines have known and quite serious side effects, including death.

134. Nurse N. also knows that in her county "fully vaccinated" patients now comprise the majority of COVID cases according to testing results (25 out of 41 cases), which is why "health experts" are now calling for "booster shots," which she fears will be demanded of her under the Vaccine Mandate, which requires that employees "continuously" be "fully vaccinated," however many times the government demands. These medical facts inform Nurse N.'s religious conviction against involuntary vaccination as an invasion of bodily autonomy that is contrary to Church teaching.

135. Plaintiff is now facing imminent loss of her employment, which is essential to the support of her family, on account of her religious abstention from COVID-19 vaccination.

136. Nurse N. will also be unemployable anywhere in the State of New York as no other hospital would hire her due to her conscientious refusal to obey the Vaccine Mandate.

137. Nurse N.'s termination will have to be reported at the time of license renewal and may well trigger disciplinary proceedings against her. There is also the threat that the DOH will make COVID-19 vaccination a condition of her license renewal.

138. Nurse N. is now also under the threat of disciplinary proceedings by the DOH, including license suspension or revocation as a further measure of coercion to take a vaccine that in her informed medical judgment she cannot take in good conscience.

139. Nurse N. will suffer imminent irreparable harm to her occupation, reputation, and professional standing in the absence of injunctive relief barring enforcement of the Vaccine Mandate.

Plaintiff "Dr. O."

140. Plaintiff O., M.D. ("Dr. O."), who is Catholic, is a board-certified General Surgeon, licensed in the State of New York. He is employed by a private hospital in the Northern District.

141. Dr. O. has treated and seen multiple patients for surgical problems (appendicitis, cholecystitis, soft tissue infections and other problems) who have had COVID.

142. On July 13, 2021, Dr. O. was granted a religious exemption from his hospital under the prior Health Order, which allowed for religious exemptions, but this has been revoked on account of the new Vaccine Mandate announced on August 26, removing the provision for religious exemptions.

143. Dr. O. has thus been advised by his employer that, because of the Vaccine Mandate, he must be "fully vaccinated" with an abortion-connected vaccine by September 21, and that "under the emergency regulations the NYS DOH will not permit exemptions or deferrals for sincerely held religious beliefs…" As the employer further advised: "any colleague who was previously approved for one of the above exemptions/deferrals [including religious exemption] will be required to provide proof of [vaccination]…"

144. Dr. O. now faces imminent loss of his privileges at the hospital where he performs surgery. Without admitting privileges, he would not be able to operate a private surgical practice as he would not have the capacity to admit patients to a hospital if need be.

145. The imminent loss of his staff position and hospital privileges will also render Dr. O. unemployable anywhere in the State of New York as no other hospital would hire him under the Vaccine Mandate, given his religiously motivated refusal to follow it.

146. The imminent loss of Dr. O's staff position and hospital privileges will have to be reported at the time of license renewal and may well trigger disciplinary proceedings against him. There is also the threat that the DOH will make COVID-19 vaccination a condition of his license renewal.

147. Dr. O. is now also under the threat of disciplinary proceedings by the DOH, including license suspension or revocation as a further measure of coercion "continuously" to be inoculated with a vaccine that in his informed medical judgment he cannot take in good conscience.

148. Dr. O. will suffer imminent irreparable harm to his occupation, reputation, and professional standing in the absence of injunctive relief barring enforcement of the Vaccine Mandate.

Plaintiff "Dr. P."

149. Plaintiff P., D.O. ("Dr. P."), who is Catholic, is a third-year obstetrics and gynecology resident at private hospital in the Western District.

150. Midway through her first year of training, the COVID-19 pandemic broke out, and Dr. P. cared for many patients infected with the virus, often with limited or no PPE. No vaccination was needed or required for her to treat patients safely.

151. In March 2020, Dr. P. was assigned to an ICU rotation, standard for a first-year resident, during which she helped care for the sickest patients in the hospital, many suffering from COVID. It was during this time that Dr. P. herself became sick with the virus, from which she recovered before returning to work.

152. As a Catholic, Dr. P. intends to practice medicine in line with the moral teachings of the Church, including the beliefs enumerated in ¶ 37 (a)-(h), which is why she chose her current residency program, in reliance on which she and her husband moved from Texas to Buffalo.

153. As a medical doctor who has recovered from COVID, Dr. P. knows that she has natural immunity, shown by numerous studies to be superior to the vaccine-induced immunity that is already fading; that the COVID vaccines now available do not limit viral transmission, as shown by the rising demand for "booster shots" (including a fourth shot in Israel); and that vaccinating a naturally immune person can do more harm than good by provoking a hyper-immune response.

154. On August 19, 2021, during the short time the prior Health Order was in effect, Dr. P. received an email from Human Resources advising that all residents must be vaccinated for COVID-19 and that "Information regarding waivers for medical or religious reasons will be

available shortly." This email also states that "disregarding the NYS Vaccination Mandate may affect your ability to continue working and training with your residency or fellowship program."

155. On August 30, 2021, Dr. P. received another email from HR advising that "Late last week, the NYS Public Health & Planning Council and the NYS Commissioner of Health *removed the religious exemption* for the recent state mandate requiring all health professionals get vaccinated for COVID-19."

156. On September 7, Dr. P. was directed to meet with the OB/GYN department chair, who attempted to pressure her into being vaccinated with the suggestion that, as she had been advised on August 19, "disregarding the NYS Vaccination Mandate may affect your ability to continue working and training with your residency or fellowship program."

157. Dr. P. now faces the imminent loss of her residency and thus destruction of her entire career as she can never become a fully licensed physician and practice independently without completing a residency.

158. Given the Vaccine Mandate, Dr. P. will be unable to find a residency anywhere in the State of New York due to her conscientious religious abstention from vaccination.

159. Further, termination of her residency for refusal to obey the Vaccine Mandate in violation of her religious belief is likely to have adverse consequences for her full licensure in New York or any other jurisdiction.

160. Dr. P. will suffer imminent irreparable harm to her occupation, reputation, and professional standing in the absence of injunctive relief barring enforcement of the Vaccine Mandate.

Plaintiff "Technologist P."

161. Plaintiff P. ("Technologist P."), who is Catholic, is a Nuclear Medicine Technologist, licensed in the State of New York, who is employed by a private health organization in the Eastern District.

162. On or about August 18, 2021, with the prior Health Order in effect, Technologist P. was advised by her employer that she must be vaccinated with a COVID vaccine unless she obtained a religious exemption, for which she applied on August 26, 2021, with extensive explanation and documentation of her sincere religious belief.

163. After the Vaccine Mandate eliminated religious exemptions on August 26, however, Technologist P. was advised by her employer by email on September 1, 2021, that her pending request for religious exemption had been rejected because "on August 26, 2021, the DOH announced that religious exemptions are not permitted under the State mandate. *It is for this reason* that we are unable to grant your request for a religious exemption."

164. Technologist P.'s employer warned in said email that she must receive at least her "first shot" of one of the abortion-connected vaccines by September 27, 2020 and that "If you choose to not receive your first shot between now and September 27, 2021, you will be non-compliant with the NYS mandate and your continued employment will be at risk."

165. Technologist P. has been further advised by her manager that, as of September 27, if she fails to be vaccinated against her religious belief, her security badge will be deactivated, she will not be able to access her place of employment and will essentially be regarded as a trespasser.

166. In addition to the medical facts recited in ¶ 37 (h), Technologist P. knows of a co-worker who collapsed after vaccination from a severe allergic reaction, requiring the calling of a

code and the administration of Benadryl and steroids for a month, and who returned to work visibly miserable, covered in a rash, itchy, jittery, and shaking. Technologist P. has also observed that 50 percent of her colleagues who contract COVID and are out sick have been "fully vaccinated," and that there is a regular flow of "fully vaccinated" patients being admitted to her hospital.

167. In addition to the medical concerns recited herein above, Technologist P. is breastfeeding, and there are limited data on the safety of COVID vaccines for the breastfeeding child, with reports of infant death following vaccination of the breastfeeding mother. These medical facts inform Technologist P.'s religious conviction against involuntary vaccination as an invasion of bodily autonomy contrary to Church teaching.

168. Technologist P. now faces imminent loss of her employment, as well as loss of her certification in disciplinary proceedings, if she refuses, as she must, any of the available COVID vaccines.

169. Any discharge from employment on account Technologist's P's conscientious and religiously motivated refusal to take any of the available abortion-connected vaccines would have to be reported upon renewal of Technologist P's certification.

170. Plaintiff Technologist P. will thus suffer imminent irreparable harm to her occupation, reputation, and professional standing in the absence of injunctive relief barring enforcement of the Vaccine Mandate.

Plaintiff "Dr. S."

171. Plaintiff S., D.D.S. ("Dr. S."), who is Catholic, is a board-certified Oral and Maxillofacial surgeon who, in addition to his private practice, is an attending physician with admitting privileges at a hospital in the Northern District.

172. Dr. S. and his partners have treated numerous patients who were sick with COVID without need of vaccination, and Dr. S. thus contracted COVID, from which he recovered. Patients with COVID were not turned away but received dental treatment that was urgently needed.

173. On August 17, 2021, under the then-applicable DOH vaccination requirement, which included the prior Health Order as of August 18, Dr. S. received a religious exemption from COVID-19 vaccination. The exemption was based on his religious convictions as a Catholic, including the beliefs enumerated above.

174. On September 1, however, Dr. S.'s religious exemption was revoked due to the issuance of the Vaccine Mandate, and he was notified by hospital administration that if he fails to provide proof of vaccination by September 21, 2021, his hospital privileges will be suspended.

175. As a licensed physician who has recovered from COVID, Dr. S. knows that he has natural immunity, shown by studies he has reviewed to be superior to the vaccine-induced immunity that is already fading. *See* Exhibit E.

176. The imminent loss of admitting privileges at the hospital with which Dr. S is affiliated will make it impossible to conduct his practice, as he cannot conduct oral and maxillofacial surgery without the ability to admit patients to a hospital if the need arises.

177. The imminent loss of privileges will also render Dr. S. unemployable anywhere in the State of New York as no other hospital would grant him privileges under the Vaccine Mandate.

178. The imminent loss of privileges will have to be reported at the time of license renewal and may well trigger disciplinary proceedings against Dr. S. There is also the threat that the DOH will make COVID-19 vaccination a condition of license renewal.

179. Dr. S. is now also under the threat of disciplinary proceedings by the DOH, including license suspension or revocation as a further measure of coercion to take a vaccine that in his informed medical judgment he cannot take in good conscience.

180. Dr. S. will suffer imminent irreparable harm to his occupation, reputation, and professional standing in the absence of injunctive relief barring enforcement of the Vaccine Mandate.

Plaintiff "Nurse S."

181. Plaintiff S., R.N. ("Nurse S."), who is Catholic, is a registered nurse employed by a hospital in the Northern District.

182. Nurse S. has treated a patient who had recovered from COVID but still decided to be vaccinated. After receiving the second dose of the vaccine, this patient needed high-flow oxygen to survive and was not able to get out of bed or even turn over without exacerbation of her condition.

183. On August 15, 2021, before the Vaccine Mandate removed religious exemptions, Nurse S. applied for a religious exemption from the employing hospital, based on the beliefs enumerated above. Nurse S.'s request for religious exemption advised in particular that she could not take any of the available COVID-19 vaccines because of their connection to aborted fetal cell lines, citing the analysis of each vaccine by the Charlotte Lozier Institute. Nurse S. advised that "is my Catholic duty to refuse the injection."

184. In addition to the medical concerns recited herein above, Nurse S. intends to have children, and she is aware that there is a lack of data on the effect of the available COVID vaccines on pregnancy and post-partum development of children, given that the vaccines have

been available for less than year. These medical facts inform Nurse S.'s religious conviction against involuntary vaccination.

185. On September 1, 2021, Nurse S. was advised by the hospital administration that due the Vaccine Mandate, as of August 26, 2021 the State will not permit exemptions for sincerely held religious beliefs, that "we are required to comply with state law" and that every member of the staff must have at least one dose of a two-dose COVID vaccine, or a single dose vaccine by September 21, 2021.

186. Nurse S., who is just beginning her nursing career, now faces imminent termination of her employment and will be unemployable as a nurse anywhere in New York State due to the Vaccine Mandate, as well as possible license suspension or disciplinary proceedings due to termination for "insubordination."

187. Nurse S. will thus suffer imminent irreparable harm to her occupation, reputation, and professional standing in the absence of injunctive relief barring enforcement of the Vaccine Mandate.

Plaintiff "Physician Liaison X."

188. Plaintiff X. ("Physician Liaison X"), who is Catholic, is a physician liaison manager for a major cancer center in the Southern District. Her job has been 100% remote for the past 18 months.

189. Last month, Physician Liaison X.'s employer began mandating COVID vaccinations for all employees, but with religious and medical exemptions allowed under the prior Health Order. That policy changed on September 1, 2021, when her employer announced by email that the Vaccine Mandate had eliminated all religious exemptions, that the employer could no longer grant religious exemptions, and that any religious exemptions granted would be

revoked. Physician Liaison X. is thus barred from obtaining the religious exemption she seeks, based on the religious beliefs enumerated above, which she holds in common with the other plaintiffs.

190. Physician Liaison X. now faces imminent loss of her employment and severe damage to her professional reputation and future employment in the extremely competitive sector of the medical executive class.

191. Physician Liaison X. will thus suffer imminent irreparable harm to her occupation, reputation, and professional standing in the absence of injunctive relief barring enforcement of the Vaccine Mandate.

COUNT I

VIOLATION OF THE FREE EXERCISE CLAUSE OF THE FIRSTAMENDMENT TO THE UNITED STATES CONSTITUTION. (42 U.S.C. § 1983)

192. Plaintiffs hereby reallege and adopt each and every allegation in paragraphs 1-191 above as if fully set forth herein.

193. The Free Exercise Clause of the First Amendment to the United States Constitution, as applied to the states by the Fourteenth Amendment, prohibits the State from abridging Plaintiffs'rights to free exercise of religion.

194. Plaintiffs have sincerely held religious beliefs that compel them to refuse vaccination with abortion-connected vaccines.

195. Plaintiffs reallege the discussion of their sincerely held religious beliefs as set forth in all the preceding paragraphs.

196. The Vaccine Mandate, on its face and as applied, targets Plaintiffs' sincerely held religious beliefs by requiring the revocation of revoking religious exemptions previously

granted by their employers or by prohibiting them from seeking and receiving exemption and accommodation for their sincerely held religious beliefs from their employers, with the employers citing the Vaccine Mandate as the grounds for refusing even to consider exemption requests.

197. The Vaccine Mandate, on its face and as applied, impermissibly burdens Plaintiffs' sincerely held religious beliefs, compels them to abandon their beliefs or violate them under coercion, and forces Plaintiffs to choose between their religious convictions and the State's patently unconstitutional value judgment that their religious beliefs are of no account and cannot be considered by employers.

198. The Vaccine Mandate strips Plaintiffs, adult medical professionals, of the right to religious exemption secured by state statute even for 17-year-old college students, who can obtain an exemption by merely submitting "a written and signed statement from the student (parent or guardian of students less than 18 years of age) that he/she objects to immunization due to his/her religious beliefs." *See* Public Health Law § 2165, Immunization Requirements for Students, https://tinyurl.com/4byd8s56.

199. The Vaccine Mandate even eliminates the protection for religion and the allowance of religious exemptions under the prior Health Order, which was revised to exclude religious accommodation on or about August 26, 2021, only days ago.

200. The Vaccine Mandate, on its face and as applied, places Plaintiffs in an irresolvable conflict between compliance with the mandate and their sincerely held religious beliefs.

201. The Vaccine Mandate, on its face and as applied, puts substantial pressure on Plaintiffs to violate their sincerely held religious beliefs or face loss of their occupations, professional standing, licenses, reputations, and ability to support their families.

202. The Vaccine Mandate, on its face and as applied, is neither neutral nor generally applicable as it grants the possibility of medical exemptions for reasons of secular "health" but bars religious exemptions according to the State's unconstitutional value judgment that physical health is less important than spiritual health.

203. The Vaccine Mandate, on its face and as applied, thus targets Plaintiffs' religious beliefs for disparate and discriminatory treatment.

204. The Vaccine Mandate, on its face and as applied, creates a system of individualized exemptions for preferred exemption requests based on physical health, while discriminating against requests for exemption and accommodation based on sincerely held religious beliefs.

205. The Vaccine Mandate, on its face and as applied, is a religious gerrymander that, only days after promulgation of the Health Order allowing religious exemptions, excluded sincerely held religious beliefs from any form of accommodation while permitting state-favored medical exemptions.

206. There is no legitimate, rational, or compelling interest in the Vaccine Mandate's exclusion of exemptions and accommodations for sincerely held religious beliefs, especially given the following facts: (a) those exempted for reasons of "health" are no less susceptible of contracting and spreading COVID (the prevention of which is the very reason for the Vaccine Mandate) than those who would be exempted for reasons of religion (b) that the available COVID-19 vaccines are clearly failing to prevent transmission or infection, so that "booster shots" are now being promoted; (c) even the vaccinated must continue to wear masks as if they were not vaccinated because they can still be infected *or infect others*; (d) that naturally immune persons who have recovered from COVID have superior immunity and do not need

vaccination; (e) that vaccinating naturally immune people may harm them by causing a hyperimmune response; and (f) that vaccinated persons are being admitted to the hospital along with unvaccinated persons.

207. The Vaccine Mandate is not the least restrictive means of achieving an otherwise permissible government interest, which could be achieved by the same protective measures (masking, testing, quarantining, etc.) already being required of the vaccinated and the unvaccinated alike (including those exempted for health reasons).

208. The Vaccine Mandate, on its face and as applied, has caused, is causing, and will continue to cause irreparable harm and actual and undue hardship to Plaintiffs from violation of their sincerely held religious beliefs and the occupational, professional, social and economic consequences pleaded above.

209. Plaintiffs have no adequate remedy at law to prevent the continuing violation of their constitutional liberties and sincerely held religious beliefs.

COUNT II

VIOLATION OF THE SUPREMACY CLAUSE OF THE UNITED STATES CONSTITUTIONBY (42 U.S.C. ¶ 1983))

210. Plaintiffs hereby reallege and adopt each and every allegation in paragraphs 1-209 as if fully set forth herein.

211. The Supremacy Clause provides:

> **This Constitution, and the Laws of the United States** which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, **shall be the supreme Law of the Land**; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Lawsof any State to the Contrary notwithstanding.

U.S. Const. Art. VI, cl. 22 (emphasis added).

212. The Vaccine Mandate, both facially and as applied, compels employers of health care workers in the State of New York to disregard Title VII's protection against employment discrimination on account of religion, forbidding any accommodation of religious belief whatsoever and even requiring the revocation of previously granted religious exemptions from COVID vaccination.

213. The Vaccine Mandate thus requires actions that federal law forbids, which renders the Vaccine Mandate null and void. *Mutual Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 486 (2013).

214. All of Plaintiffs' employers have 15 or more employees and are subject to the requirements of Title VII.

215. By attempting to preclude application of Title VII in the State of New York in the case of COVID vaccination, the Vaccine Mandate patently violates the Supremacy Clause.

216. In particular, the Vaccine Mandate purports to negate Title VII's requirement that employers provide reasonable accommodations to individuals with sincerely held religious beliefs, and even flatly prohibits religious exemption or accommodation requests, as the employers noted above have indicated.

217. By purporting to place themselves and their mandate outside the protections of both Title VII and the First Amendment, Defendants have violated the basic constitutional principle that "federal law is as much the law of the several States as are the laws passed by their legislatures." *Haywood v. Drown*, 556 U.S. 729, 734 (2009) (emphasis added).

218. The Vaccine Mandate, on its face and as applied, has caused, is causing, and will continue to cause irreparable harm and actual and undue hardship to Plaintiffs from violation of

their sincerely held religious beliefs and the occupational, professional, social and economic consequences pleaded above.

219. Plaintiffs have no adequate remedy at law for the continuing deprivation of their statutory rights under Title VII as secured by the Supremacy Clause.

COUNT III

VIOLATION OF THE EQUAL PROTECTION CLAUSE OF THE FOURTEENTH AMENDMENT TO THE UNITED STATES CONSTITUTION (42 U.S.C. § 1983)

220. Plaintiffs hereby reallege and adopt each and every allegation in paragraphs 1-209 above as if fully set forth herein.

221. The Fourteenth Amendment to the United States Constitution guarantees Plaintiffs' right to equal protection under the law.

222. The Vaccine Mandate, on its face and as applied, is an unconstitutional abridgment of Plaintiffs' right to equal protection, is not neutral, and specifically targets Plaintiffs' sincerely held religious beliefs for discriminatory and unequal treatment as compared with the medical exemptions favored by the State's impermissible, anti-religious value judgment.

223. The Vaccine Mandate, on its face and as applied, is an unconstitutional abridgement of Plaintiffs' right to equal protection because it permits the State to treat Plaintiffs differently from similarly situated healthcare workers solely on the basis of Plaintiffs' sincerely held religious beliefs.

224. The Vaccine Mandate, on its face and as applied, singles out Plaintiffs for selective treatment based upon their sincerely held religious objections to the COVID-19 vaccines.

225. The Vaccine Mandate, on its face and as applied, was clearly designed to slam shut what Defendants undoubtedly viewed as a large potential "escape hatch" from their planned regime of brute coercion to be vaccinated under penalty of personal and professional destruction, which regime has no precedent in the history of the United States. This is shown by the Vaccine Mandate's abrupt excision of religious protection and religious accommodation from the prior Health Order, issued only days before. The intent is clearly to leave religious believers with no choice but to violate their religious beliefs to keep their jobs and avoid professional destruction and financial hardship.

226. The Vaccine Mandate, on its face and as applied, creates a system of classes and categories that improperly accommodates exemptions for the class of healthcare workers concerned with bodily health while denying exemption to the class of health care workers concerned with spiritual health above bodily health, including all the Plaintiffs herein.

227. The Vaccine Mandate, reversing the State's policy of only days before, arbitrarily and capriciously attempts to deny Plaintiffs and others similarly situated the protection for religion and the requirement of religious accommodation under both the Human Rights Law of the State of New York and the Human Rights Law of the City of New York, as well as the parallel the protections of Title VII, while leaving untouched protections under the same statutes for other protected classes, including by allowing exemptions for reasons of "health" but not religion.

228. The Vaccine Mandate arbitrarily and capriciously denies to adult medical workers with expert knowledge of vaccination and its risks the same religious exemption from vaccination available to any college student under Public Health Law § 2615, as pleaded above.

229. By purporting to negate statutorily required religious accommodations from consideration in the State of New York, Defendants, via the Vaccine Mandate, have singled out for disparate treatment the specific class of healthcare employees whose motive for seeking exemption from vaccination is religious rather than medical.

230. Further, Nurse J, Nurse N, Dr. P, and Dr. S have all previously had COVID or COVID-like symptoms and, on information and belief, have natural immunity at a level no less than, and likely far more than, the immunity purportedly offered by available COVID vaccines. (See Exhibit E.)

231. There is no rational, legitimate, or compelling interest in the Vaccine Mandate's application of different standards to different, similarly situated groups in the field of healthcare.

232. The Vaccine Mandate, on its face and as applied, discriminates between religion and nonreligion by allowing nonreligious exemptions to the Vaccine Mandate while prohibiting religious exemptions.

233. The Vaccine Mandate, on its face and as applied, is a "status-based enactment divorced from any factual context" and "a classification of persons undertaken for its own sake," which "the Equal Protection Clause does not permit." *Romer v. Evans*, 517 U.S. 620, 635 (1996). The Vaccine Mandate, on its face and as applied, "identifies persons by a single trait [religious beliefs] and then denies them protections across the board." *Id.*at 633.

234. The Vaccine Mandate, on its face and as applied, by allowing medical exemptions while denying religious exemptions, is a "disqualification of a class of persons from the right to seek specific protection [for their religious beliefs]." *Id.*

235. "A law declaring that in general it shall be more difficult for one group of citizens than for all others to seek [an exemption from the COVID-19 Vaccine Mandate] is itself a

denial of equal protection of the laws in the most literal sense." *Id.* The Vaccine Mandate, on its face and as applied, is such a measure.

236. The Vaccine Mandate, on its face and as applied, has caused, is causing, and will continue to cause irreparable harm and actual and undue hardship to Plaintiffs from violation of their sincerely held religious beliefs and the occupational, professional, social and economic consequences pleaded above.

237. Plaintiffs have no adequate remedy at law for the continuing deprivation of their rights under the Equal Protection Clause.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for relief as follows as to all Counts:

(A). A statewide temporary restraining order and/or preliminary injunction, followed by a permanent injunction, restraining and enjoining the Defendants, their officers, agents, employees, attorneys and successors in office, and all other persons in active concert or participation with them, from enforcing, threatening to enforce, attempting to enforce, or otherwise requiring compliance with the Vaccine Mandate such that:

(1) The Vaccine Mandate is suspended in operation to the extent that the Department of Health is barred from enforcing any requirement that employers deny religious exemptions from COVID-19 vaccination or that they revoke any exemptions employers already granted before the Vaccine Mandate superseded the prior Health Order to exclude religious exemptions, including the exemptions already granted to certain of the Plaintiffs herein;

(2) The Department of Health is barred from interfering in any way with the granting of religious exemptions from COVID-19 vaccination going forward, or with the operation of exemptions already granted under the prior Health Order;

(3) The Department of Health is barred from taking any action, disciplinary or otherwise, against the licensure, certification, residency, admitting privileges or other professional status or qualification of any of the Plaintiffs on account of their seeking or having obtained a religious exemption from mandatory COVID-19 vaccination.

(B). A declaratory judgment declaring that the Vaccine Mandate, both on its face and as applied by Defendants, is unconstitutional, unlawful, and unenforceable in that:

(1) the Vaccine Mandate violates the Free Exercise Clause of the First Amendment by depriving Plaintiffs and others similarly situated of the free exercise of religion under a measure that is neither neutral nor generally applicable but rather favors secular over religious reasons for exemption from COVID-19 vaccination and specifically targets for elimination the religious exemptions provided only days earlier under the superseded Health Order;

(2) the Vaccine Mandate violates the Supremacy Clause by purporting to strip Plaintiff and others similarly situated of statutory and constitutional protections for religion and religious accommodation under federal law;

(3) the Vaccine Mandate violates the Equal Protection Clause of the Fourteenth Amendment by purporting to strip Plaintiffs and others similarly situated of state and federal statutory protection from discrimination in the matter of vaccination solely because of the religious grounds on which Plaintiffs seek protection.

(C). An award of reasonable costs and expenses of this action, including a reasonable attorney's fee, in accordance with 42 U.S.C. § 1988; and

(D). Such other and further relief as the Court deems equitable and just under the circumstances.

Dated: September 13, 2021

Respectfully submitted,

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VERIFICATION

I, Dr. A, am over the age of 18 and am a Plaintiff in this action. The allegations that pertain to me in this VERIFIED COMPLAINT are true and correct, based upon my personal knowledge (unless otherwise indicated), and if called upon to testify as to their truthfulness, I would and could do so competently. I declare under penalties of perjury, under the laws of the United States, that the foregoing statements are true and correct.

Executed on September 9TH 2021

Dr. A

VERIFICATION

I, Dr. C, am over the age of 18 and am a Plaintiff in this action. The allegations that pertain to me in this VERIFIED COMPLAINT are true and correct, based upon my personal knowledge (unless otherwise indicated), and if called upon to testify as to their truthfulness, I would and could do so competently. I declare under penalties of perjury, under the laws of the United States, that the foregoing statements are true and correct.

Executed on 9-9-2021

[signature]

VERIFICATION

I, Dr. F, am over the age of 18 and am a Plaintiff in this action. The allegations that pertain to me in this VERIFIED COMPLAINT are true and correct, based upon my personal knowledge (unless otherwise indicated), and if called upon to testify as to their truthfulness, I would and could do so competently. I declare under penalties of perjury, under the laws of the United States, that the foregoing statements are true and correct.

Executed on 9-9-2021

Dr F

VERIFICATION

I, [redacted] am over the age of 18 and am a Plaintiff in this action. The allegations that pertain to me in this VERIFIED COMPLAINT are true and correct, based upon my personal knowledge (unless otherwise indicated), and if called upon to testify as to their truthfulness, I would and could do so competently. I declare under penalties of perjury, under the laws of the United States, that the foregoing statements are true and correct.

Executed on 9/7/2024

[redacted]

Dr. G.

VERIFICATION

I, Dr. J, am over the age of 18 and am a Plaintiff in this action. The allegations that pertain to me in this VERIFIED COMPLAINT are true and correct, based upon my personal knowledge (unless otherwise indicated), and if called upon to testify as to their truthfulness, I would and could do so competently. I declare under penalties of perjury, under the laws of the United States, that the foregoing statements are true and correct.

Executed on 9/11/21

Dr. J.

VERIFICATION

I, Dr. M, am over the age of 18 and a Plaintiff in this action. The allegations that pertain to me in this VERIFIED COMPLAINT are true and correct. based upon my personal knowledge (unless otherwise indicated), and if called upon to testify as to their truthfulness. I would and could do so competently. I declare under penalties of perjury, under the laws of the United States. that the foregoing statements are true and correct.

Executed on 9/12/2021

Dr. M.

VERIFICATION

I, [redacted], am over the age of 18 and am a Plaintiff in this action. The allegations that pertain to me in this VERIFIED COMPLAINT are true and correct, based upon my personal knowledge (unless otherwise indicated), and if called upon to testify as to their truthfulness, I would and could do so competently. I declare under penalties of perjury, under the laws of the United States, that the foregoing statements are true and correct.

Executed on 9/9/2021

[redacted]

Dr. O

VERIFICATION

I, Dr. P, am over the age of 18 and am a Plaintiff in this action. The allegations that pertain to me in this VERIFIED COMPLAINT are true and correct, based upon my personal knowledge (unless otherwise indicated), and if called upon to testify as to their truthfulness, I would and could do so competently. I declare under penalties of perjury, under the laws of the United States, that the foregoing statements are true and correct.

Executed on September 10, 2021

Dr. P

VERIFICATION

I, Dr. S, am over the age of 18 and am a Plaintiff in this action. The allegations that pertain to me in this VERIFIED COMPLAINT are true and correct, based upon my personal knowledge (unless otherwise indicated), and if called upon to testify as to their truthfulness, I would and could do so competently. I declare under penalties of perjury, under the laws of the United States, that the foregoing statements are true and correct.

Executed on 9/9/21

S

Dr. S

VERIFICATION

I, Nurse A, am over the age of 18 and am a Plaintiff in this action. The allegations that pertain to me in this VERIFIED COMPLAINT are true and correct, based upon my personal knowledge (unless otherwise indicated), and if called upon to testify as to their truthfulness, I would and could do so competently. I declare under penalties of perjury, under the laws of the United States, that the foregoing statements are true and correct.

Executed on 9/11/21

Nurse A.

VERIFICATION

I, [redacted], am over the age of 18 and am a Plaintiff in this action. The allegations that pertain to me in this VERIFIED COMPLAINT are true and correct, based upon my personal knowledge (unless otherwise indicated), and if called upon to testify as to their truthfulness, I would and could do so competently. I declare under penalties of perjury, under the laws of the United States, that the foregoing statements are true and correct.

Executed on 9/9/21 [redacted]

Nurse D

- **VERIFICATION**

I, Nurse J, am over the age of 18 and am a Plaintiff in this action. The allegations that pertain to me in this VERIFIED COMPLAINT are true and correct, based upon my personal knowledge (unless otherwise indicated), and if called upon to testify as to their truthfulness, I would and could do so competently. I declare under penalties of perjury, under the laws of the United States, that the foregoing statements are true and correct.

Executed on 9/9/2021

Nurse J

VERIFICATION

I, Nurse N, am over the age of 18 and am a Plaintiff in this action. The allegations that pertain to me in this VERIFIED COMPLAINT are true and correct, based upon my personal knowledge (unless otherwise indicated), and if called upon to testify as to their truthfulness, I would and could do so competently. I declare under penalties of perjury, under the laws of the United States, that the foregoing statements are true and correct.

Executed on Sept 11, 2021

Nurse N

VERIFICATION

I, Nurse S, am over the age of 18 and am a Plaintiff in this action. The allegations that pertain to me in this VERIFIED COMPLAINT are true and correct, based upon my personal knowledge (unless otherwise indicated), and if called upon to testify as to their truthfulness, I would and could do so competently. I declare under penalties of perjury, under the laws of the United States, that the foregoing statements are true and correct.

Executed on 9/10/21

Nurse S

VERIFICATION

I, Physician Liaison X, am over the age of 18 and am a Plaintiff in this action. The allegations that pertain to me in this VERIFIED COMPLAINT are true and correct, based upon my personal knowledge (unless otherwise indicated), and if called upon to testify as to their truthfulness, I would and could do so competently. I declare under penalties of perjury, under the laws of the United States, that the foregoing statements are true and correct.

Executed on 9/12/21

Physician Liaison X

VERIFICATION

I, Technologist P., am over the age of 18 and am a Plaintiff in this action. The allegations that pertain to me in this VERIFIED COMPLAINT are true and correct, based upon my personal knowledge (unless otherwise indicated), and if called upon to testify as to their truthfulness, I would and could do so competently. I declare under penalties of perjury, under the laws of the United States, that the foregoing statements are true and correct.

Executed on 9/9/2021

Technologist P.

Technologist P.

VERIFICATION

I, Therapist I, am over the age of 18 and am a Plaintiff in this action. The allegations that pertain to me in this VERIFIED COMPLAINT are true and correct, based upon my personal knowledge (unless otherwise indicated), and if called upon to testify as to their truthfulness, I would and could do so competently. I declare under penalties of perjury, under the laws of the United States, that the foregoing statements are true and correct.

Executed on 10 SEPTEMBER 2021

Therapist I

Therapist I

EXHIBIT A

EXHIBIT A

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Public Health Law Sections 225, 2800, 2803, 3612, and 4010, as well as Social Services Law Sections 461 and 461-e, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, is amended, to be effective upon filing with the Department of State, to read as follows:

Part 2 is amended to add a new section 2.61, as follows:

2.61. Prevention of COVID-19 transmission by covered entities.

(a) Definitions.

(1) "Covered entities" for the purposes of this section, shall include:

(i) any facility or institution included in the definition of "hospital" in section 2801 of the Public Health Law, including but not limited to general hospitals, nursing homes, and diagnostic and treatment centers;

(ii) any agency established pursuant to Article 36 of the Public Health Law, including but not limited to certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies;

(iii) hospices as defined in section 4002 of the Public Health Law; and

(iv) adult care facility under the Department's regulatory authority, as set forth in Article 7 of the Social Services Law.

(2) “Personnel,” for the purposes of this section, shall mean all persons employed or affiliated with a covered entity, whether paid or unpaid, including but not limited to employees, members of the medical and nursing staff, contract staff, students, and volunteers, who engage in activities such that if they were infected with COVID-19, they could potentially expose other covered personnel, patients or residents to the disease.

(3) “Fully vaccinated,” for the purposes of this section, shall be determined by the Department in accordance with applicable federal guidelines and recommendations. Unless otherwise specified by the Department, documentation of vaccination must include the manufacturer, lot number(s), date(s) of vaccination; and vaccinator or vaccine clinic site, in one of the following formats:

(i) record prepared and signed by the licensed health practitioner who administered the vaccine, which may include a CDC COVID-19 vaccine card;

(ii) an official record from one of the following, which may be accepted as documentation of immunization without a health practitioner’s signature: a foreign nation, NYS Countermeasure Data Management System (CDMS), the NYS Immunization Information System (NYSIIS), City Immunization Registry (CIR), a Department-recognized immunization registry of another state, or an electronic health record system; or

(iii) any other documentation determined acceptable by the Department.

(c) Covered entities shall continuously require personnel to be fully vaccinated against COVID-19, with the first dose for current personnel received by September 27, 2021 for general hospitals and nursing homes, and by October 7, 2021 for all other covered entities absent receipt of an exemption as allowed below. Documentation of such vaccination shall be made in personnel records or other appropriate records in accordance with applicable privacy laws, except as set forth in subdivision (d) of this section.

(d) Exemptions. Personnel shall be exempt from the COVID-19 vaccination requirements set forth in subdivision (c) of this section as follows:

(1) Medical exemption. If any licensed physician or certified nurse practitioner certifies that immunization with COVID-19 vaccine is detrimental to the health of member of a covered entity's personnel, based upon a pre-existing health condition, the requirements of this section relating to COVID-19 immunization shall be inapplicable only until such immunization is found no longer to be detrimental to such personnel member's health. The nature and duration of the medical exemption must be stated in the personnel employment medical record, or other appropriate record, and must be in accordance with generally accepted medical standards, (see, for example, the recommendations of the Advisory Committee on Immunization Practices of the U.S. Department of Health and Human Services), and any reasonable accommodation may be granted and must likewise be documented in such record. Covered entities shall document medical exemptions in personnel records or other appropriate records in accordance with applicable privacy laws by: (i) September 27, 2021 for general hospitals and nursing homes; and (ii) October 7,

2021 for all other covered entities. For all covered entities, documentation must occur continuously, as needed, following the initial dates for compliance specified herein, including documentation of any reasonable accommodation therefor.

(e) Upon the request of the Department, covered entities must report and submit documentation, in a manner and format determined by the Department, for the following:

(1) the number and percentage of personnel that have been vaccinated against COVID-19;

(2) the number and percentage of personnel for which medical exemptions have been granted;

(3) the total number of covered personnel.

(f) Covered entities shall develop and implement a policy and procedure to ensure compliance with the provisions of this section and submit such documents to the Department upon request.

(g) The Department may require all personnel, whether vaccinated or unvaccinated, to wear an appropriate face covering for the setting in which such personnel are working in a covered entity. Covered entities shall supply face coverings required by this section at no cost to personnel.

Subparagraph (vi) of paragraph (10) of subdivision (b) of Section 405.3 of Part 405 is added to read as follows:

(vi) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation immediately available upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (5) of subdivision (a) of Section 415.19 of Part 415 is added to read as follows:

(5) collects documentation of COVID-19 or documentation of a valid medical exemption to such vaccination, for all personnel pursuant to section 2.61 of this title, in accordance with applicable privacy laws, and making such documentation immediately available upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (7) of subdivision (d) of Section 751.6 is added to read as follows:

(7) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department , as well as any reasonable accommodation addressing such exemption.

Paragraph (6) of subdivision (c) of Section 763.13 is added to read as follows:

(6) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making

such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (7) of subdivision (d) of Section 766.11 is added to read as follows:

(7) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (8) of subdivision (d) of Section 794.3 is added to read as follows:

(8) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (v) of subdivision (q) of Section 1001.11 is added to read as follows:

(v) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

EXHIBIT A

Paragraph (18) of subdivision (a) of Section 487.9 of Title 18 is added to read as follows:

(18) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of Title 10, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (14) of subdivision (a) of Section 488.9 of Title 18 is added to read as follows:

(14) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of Title 10, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

Paragraph (15) of subdivision (a) of Section 490.9 of Title 18 is added to read as follows:

(15) Operator shall collect documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of Title 10, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

EXHIBIT A

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of these regulations is contained in Public Health Law (PHL) Sections 225(5), 2800, 2803(2), 3612 and 4010 (4). PHL 225(5) authorizes the Public Health and Health Planning Council (PHHPC) to issue regulations in the State Sanitary Code pertaining to any matters affecting the security of life or health or the preservation and improvement of public health in the state of New York, including designation and control of communicable diseases and ensuring infection control at healthcare facilities and any other premises.

PHL Article 28 (Hospitals), Section 2800 specifies that "hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state, pursuant to section three of article seventeen of the constitution, the department of health shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services, and all public and private institutions, whether state, county, municipal, incorporated or not incorporated, serving principally as facilities for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition or for the rendering of health-related service shall be subject to the provisions of this article."

PHL Section 2803(2) authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities.

PHL Section 3612 authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, with respect to certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies. PHL Section 4010 (4) authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, with respect to hospice organizations.

Social Service Law (SSL) Section 461 requires the Department to promulgate regulations establishing general standards applicable to Adult Care Facilities (ACF). SSL Section 461-e authorizes the Department to promulgate regulations to require adult care facilities to maintain certain records with respect to the facilities residents and the operation of the facility.

Legislative Objectives:

The legislative objective of PHL Section 225 empowers PHHPC to address any issue affecting the security of life or health or the preservation and improvement of public health in the state of New York, including designation and control of communicable diseases and ensuring infection control at healthcare facilities and any other premises. PHL Article 28 specifically addresses the protection of the health of the residents of the State by assuring the efficient provision and proper utilization of health services of the highest quality at a reasonable cost. PHL Article 36 addresses the services rendered by certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies. PHL Article 40 declares that hospice is a socially and financially beneficial alternative to conventional

curative care for the terminally ill. Lastly, the legislative objective of SSL Section 461 is to promote the health and well-being of residents of ACFs.

Needs and Benefits:

The Centers for Disease Control and Prevention (CDC) has identified a concerning national trend of increasing circulation of the SARS-CoV-2 Delta variant. Since early July, cases have risen 10-fold, and 95 percent of the sequenced recent positives in New York State were the Delta variant. Recent New York State data show that unvaccinated individuals are approximately 5 times as likely to be diagnosed with COVID-19 compared to vaccinated individuals. Those who are unvaccinated have over 11 times the risk of being hospitalized with COVID-19.

The COVID-19 vaccines are safe and effective. They offer the benefit of helping to reduce the number of COVID-19 infections, including the Delta variant, which is a critical component to protecting public health. Certain settings, such as healthcare facilities and congregate care settings, pose increased challenges and urgency for controlling the spread of this disease because of the vulnerable patient and resident populations that they serve. Unvaccinated personnel in such settings have an unacceptably high risk of both acquiring COVID-19 and transmitting the virus to colleagues and/or vulnerable patients or residents, exacerbating staffing shortages, and causing unacceptably high risk of complications.

In response to this significant public health threat, through this emergency regulation, the Department is requiring covered entities to ensure their personnel are fully vaccinated against COVID-19, and to document evidence thereof in appropriate records. Covered entities are also required to review and make determinations on medical exemption requests, and provide

reasonable accommodations therefor to protect the wellbeing of the patients, residents and personnel in such facilities. Documentation and information regarding personnel vaccinations as well as exemption requests granted are required to be provided to the Department immediately upon request.

Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity:

Covered entities must ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. Covered entities must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records, as well as any reasonable accommodations. This is a modest investment to protect the health and safety of patients, residents, and personnel, especially when compared to both the direct medical costs and indirect costs of personnel absenteeism.

Cost to State and Local Government:

The State operates several healthcare facilities subject to this regulation. Most county health departments are licensed under Article 28 or Article 36 of the PHL and are therefore also subject to regulation. Similarly, certain counties and the City of New York operate facilities licensed under Article 28. These State and local public facilities would be required to ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. They must also review and make determinations on requests for

medical exemptions, which must also be documented in personnel or other appropriate records, along with any reasonable accommodations.

Although the costs to the State or local governments cannot be determined with precision, the Department does not expect these costs to be significant. State facilities should already be ensuring COVID-19 vaccination among their personnel, subject to State directives. Further, these entities are expected to realize savings as a result of the reduction in COVID-19 in personnel and the attendant loss of productivity and available staff.

Cost to the Department of Health:

There are no additional costs to the State or local government, except as noted above. Existing staff will be utilized to conduct surveillance of regulated parties and to monitor compliance with these provisions.

Local Government Mandates:

Covered entities operated by local governments will be subject to the same requirements as any other covered entity subject to this regulation.

Paperwork:

This measure will require covered entities to ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. Covered entities must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records along with any reasonable accommodations.

Upon the request of the Department, covered entities must report the number and percentage of total covered personnel, as well as the number and percentage that have been vaccinated against COVID-19 and those who have been granted a medical exemption, along with any reasonable accommodations. Facilities and agencies must develop and implement a policy and procedure to ensure compliance with the provisions of this section, making such documents available to the Department upon request.

Duplication:

This regulation will not conflict with any state or federal rules.

Alternative Approaches:

One alternative would be to require covered entities to test all personnel in their facility before each shift worked. This approach is limited in its effect because testing only provides a person's status at the time of the test and testing every person in a healthcare facility every day is impractical and would place an unreasonable resource and financial burden on covered entities if PCR tests couldn't be rapidly turned around before the commencement of the shift. Antigen tests have not proven as reliable for asymptomatic diagnosis to date.

Another alternative to requiring covered entities to mandate vaccination would be to require covered entities to mandate all personnel to wear a fit-tested N95 face covering at all times when in the facility, in order to prevent transmission of the virus. However, acceptable face coverings, which are not fit-tested N95 face coverings have been a long-standing requirement in these covered entities, and, while helpful to reduce transmission it does not prevent transmission

and; therefore, masking in addition to vaccination will help reduce the numbers of infections in these settings even further.

Federal Requirements:

There are no minimum standards established by the federal government for the same or similar subject areas.

Compliance Schedule:

These proposed emergency regulations will become effective upon filing with the Department of State and will expire, unless renewed, 90 days from the date of filing. As the COVID-19 pandemic is consistently and rapidly changing, it is not possible to determine the expected duration of need at this point in time. The Department will continuously evaluate the expected duration of these emergency regulations throughout the aforementioned 90-day effective period in making determinations on the need for continuing this regulation on an emergency basis or issuing a notice of proposed ruling-making for permanent adoption. This notice does not constitute a notice of proposed or revised rule making for permanent adoption.

Contact Person:

Ms. Katherine E. Ceroalo
NYS Department of Health
Bureau of House Counsel, Regulatory Affairs Unit
Corning Tower Building, Room 2438
Empire State Plaza
Albany, NY 12237
(518) 473-7488
(518) 473-2019 –FAX
REGSQNA@health.state.ny.us

EXHIBIT A

REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

This regulation will not impact local governments or small businesses unless they operate a covered entity as defined in the proposed emergency regulation. Currently, 5 general hospitals, 79 nursing homes, 75 certified home health agencies (CHHAs), 20 hospices and 1,055 licensed home care service agencies (LHCSAs), and 483 adult care facilities (ACFs) are small businesses (defined as 100 employees or less), independently owned and operated affected by this rule. Local governments operate 19 hospitals, 137 diagnostic and treatment facilities, 21 nursing homes, 12 CHHAs, at least 48 LHCSAs, 1 hospice, and 2 ACFs.

Compliance Requirements:

Covered entities are required to ensure their personnel are fully vaccinated against COVID-19, and to document evidence thereof in appropriate records. Covered entities are also required to review and make determinations on medical exemption requests, along with any reasonable accommodations.

Upon the request of the Department, covered entities must report the number and percentage of total covered personnel, as well as the number and percentage that have been vaccinated against COVID-19 and those who have been granted a medical exemption, along with any reasonable accommodations. Facilities and agencies must develop and implement a policy and procedure to ensure compliance with the provisions of this section, making such documents available to the Department upon request.

Professional Services:

There are no additional professional services required as a result of this regulation.

Compliance Costs:

Covered entities must ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. Covered entities must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records, along with any reasonable accommodations. This is a modest investment to protect the health and safety of patients, residents, and personnel, especially when compared to both the direct medical costs and indirect costs of personnel absenteeism.

Economic and Technological Feasibility:

There are no economic or technological impediments to the rule changes.

Minimizing Adverse Impact:

As part of ongoing efforts to address the COVID-19 pandemic, regulated parties have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19 within the Department since March of 2020. Further, the Department currently has an emergency regulation in place, which requires nursing homes and adult care facilities to offer COVID-19 vaccination to personnel and residents, which has helped to facilitated vaccination of personnel. Further, it is the Department's understanding that many facilities across the State have begun to impose mandatory vaccination policies. Lastly, on August 18, 2021, President Biden announced that as a condition of participating in the Medicare and Medicaid programs, the United States Department of Health and Human Services will be developing regulations requiring nursing homes to mandate COVID-19 vaccination for workers.

Small Business and Local Government Participation:

Due to the emergent nature of COVID-19, small businesses and local governments were not consulted. If these regulations are proposed for permanent adoption, all parties will have an opportunity to provide comments during the notice and comment period.

EXHIBIT A

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

While this rule applies uniformly throughout the state, including rural areas, for the purposes of this Rural Area Flexibility Analysis (RAFA), "rural area" means areas of the state defined by Exec. Law § 481(7) (SAPA § 102(10)). Per Exec. Law § 481(7), rural areas are defined as "counties within the state having less than two hundred thousand population, and the municipalities, individuals, institutions, communities, and programs and such other entities or resources found therein. In counties of two hundred thousand or greater population 'rural areas' means towns with population densities of one hundred fifty persons or less per square mile, and the villages, individuals, institutions, communities, programs and such other entities or resources as are found therein."

The following 42 counties have an estimated population of less than 200,000 based upon 2019 United States Census projections:

Allegany County	Greene County	Schuyler County
Broome	Hamilton County	Seneca County
Cattaraugus County	Herkimer County	St. Lawrence County
Cayuga County	Jefferson County	Steuben County
Chautauqua County	Lewis County	Sullivan County
Chemung County	Livingston County	Tioga County
Chenango County	Madison County	Tompkins County
Clinton County	Montgomery County	Ulster County
Columbia County	Ontario County	Warren County
Cortland County	Orleans County	
Delaware County	Schoharie County	

Essex County	Oswego County	Washington County
Franklin County	Otsego County	Wayne County
Fulton County	Putnam County	Wyoming County
Genesee County	Rensselaer County	Yates County
	Schenectady County	

The following counties of have population of 200,000 or greater, and towns with population densities of 150 person or fewer per square mile, based upon 2019 United States Census population projections:

Albany County	Niagara County	Saratoga County
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga County	
Monroe County	Orange County	

Reporting, recordkeeping, and other compliance requirements; and professional services:

Covered entities are required to ensure their personnel are fully vaccinated against COVID-19, and to document evidence thereof in appropriate records. Covered entities are also required to review and make determinations on medical exemption requests, along with any reasonable accommodations.

Upon the request of the Department, covered entities must report the number and percentage of total covered personnel, as well as the number and percentage that have been vaccinated against COVID-19 and those who have been granted a medical exemption, along with any reasonable accommodations. Facilities and agencies must develop and implement a policy

and procedure to ensure compliance with the provisions of this section, making such documents available to the Department upon request.

Compliance Costs:

Covered entities must ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. Covered entities must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records, along with any reasonable accommodations. This is a modest investment to protect the health and safety of patients, residents, and personnel, especially when compared to both the direct medical costs and indirect costs of personnel absenteeism.

Minimizing Adverse Impact:

As part of ongoing efforts to address the COVID-19 pandemic, regulated parties have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19 within the Department since March of 2020. Further, the Department currently has an emergency regulation in place, which requires nursing homes and adult care facilities to offer COVID-19 vaccination to personnel and residents, which has helped to facilitated vaccination of personnel. Further, it is the Department's understanding that many facilities across the State have begun to impose mandatory vaccination policies. Lastly, on August 18, 2021, President Biden announced that as a condition of participating in the Medicare and Medicaid programs, the United States Department of Health and Human Services will be developing regulations requiring nursing homes to mandate COVID-19 vaccination for workers.

Rural Area Participation:

Due to the emergent nature of COVID-19, parties representing rural areas were not consulted. If these regulations are proposed for permanent adoption, all parties will have an opportunity to provide comments during the notice and comment period.

EXHIBIT A

JOB IMPACT STATEMENT

Nature of Impact:

Covered entities may terminate personnel who are not fully vaccinated and do not have a valid medical exemption and are unable to otherwise ensure individuals are not engaged in patient/resident care or expose other covered personnel.

Categories and numbers affected:

This rule may impact any individual who falls within the definition of "personnel" who is not fully vaccinated against COVID-19 and does not have a valid medical exemption on file with the covered entity for which they work or are affiliated.

Regions of adverse impact:

The rule would apply uniformly throughout the State and the Department does not anticipate that there will be any regions of the state where the rule would have a disproportionate adverse impact on jobs or employment.

Minimizing adverse impact:

As part of ongoing efforts to address the COVID-19 pandemic, regulated parties have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19 within the Department since March of 2020. Further, the Department currently has an emergency regulation in place, which requires nursing homes and adult care facilities to offer COVID-19 vaccination to personnel and residents, which has helped to facilitated vaccination of personnel. Further, it is the Department's understanding that many facilities across the State

have begun to impose mandatory vaccination policies. Lastly, on August 18, 2021, President Biden announced that as a condition of participating in the Medicare and Medicaid programs, the United States Department of Health and Human Services will be developing regulations requiring nursing homes to mandate COVID-19 vaccination for workers.

EXHIBIT A

EMERGENCY JUSTIFICATION

The Centers for Disease Control and Prevention (CDC) has identified a concerning national trend of increasing circulation of the SARS-CoV-2 Delta variant. Since early July, cases have risen 10-fold, and 95 percent of the sequenced recent positives in New York State were the Delta variant. Recent New York State data show that unvaccinated individuals are approximately 5 times as likely to be diagnosed with COVID-19 compared to vaccinated individuals. Those who are unvaccinated have over 11 times the risk of being hospitalized with COVID-19.

The COVID-19 vaccines are safe and effective. They offer the benefit of helping to reduce the number of COVID-19 infections, including the Delta variant, which is a critical component to protecting public health. Certain settings, such as healthcare facilities and congregate care settings, pose increased challenges and urgency for controlling the spread of this disease because of the vulnerable patient and resident populations that they serve. Unvaccinated personnel in such settings have an unacceptably high risk of both acquiring COVID-19 and transmitting the virus to colleagues and/or vulnerable patients or residents, exacerbating staffing shortages, and causing unacceptably high risk of complications.

In response to this significant public health threat, through this emergency regulation, the Department is requiring covered entities to ensure their personnel are fully vaccinated against COVID-19, and to document evidence thereof in appropriate records. Covered entities are also required to review and make determinations on medical exemption requests, and provide reasonable accommodations therefor to protect the wellbeing of the patients, residents and personnel in such facilities. Documentation and information regarding personnel vaccinations as well as exemption requests granted are required to be provided to the Department immediately upon request.

Based on the foregoing, the Department has determined that these emergency regulations are necessary to control the spread of COVID-19 in the identified regulated facilities or entities. As described above, current circumstances and the risk of spread to vulnerable resident and patient populations by unvaccinated personnel in these settings necessitate immediate action and, pursuant to the State Administrative Procedure Act Section 202(6), a delay in the issuance of these emergency regulations would be contrary to public interest.

EXHIBIT B

EXHIBIT B

STATE OF NEW YORK : DEPARTMENT OF HEALTH

IN THE MATTER

OF

COVERED ENTITIES IN THE PREVENTION AND CONTROL OF THE 2019 NOVEL CORONAVIRUS

ORDER FOR SUMMARY ACTION

WHEREAS the 2019 Novel Coronavirus ("COVID-19") is an infection associated with fever and signs and symptoms of pneumonia and other respiratory illness that is easily transmitted from person to person, predominantly through droplet transmission, and has significant public health consequences; and

WHEREAS COVID-19 is a global pandemic that, to date, has resulted in 2,195,903 documented cases and 43,277 deaths in New York State alone; and

WHEREAS the Centers for Disease Control and Prevention (CDC) has identified a concerning national trend of increasing circulation of the Delta COVID-19 variant; and

WHEREAS the U.S. Food and Drug Administration (FDA) granted Emergency Use Authorizations (EUA) for Pfizer -BioNTech, Moderna, and Janssen COVID-19 vaccines which have been shown to be safe and effective as determined by data from the manufacturers and findings from large clinical trials; and

WHEREAS while New York State has aggressively promoted vaccination since COVID-19 vaccines first became available in December 2020, current vaccination rates are not high enough to prevent the spread of the Delta variant, which is approximately twice as transmissible as the original SARS-CoV-2 strain; and

WHEREAS data show that unvaccinated individuals are approximately 5 times as likely to be diagnosed with COVID-19 as are vaccinated individuals; and

WHEREAS those who are unvaccinated have over 10 times the risk of being seriously ill and hospitalized with COVID-19; and

WHEREAS since early July, cases have risen 10-fold, and 95 percent of sequenced recent positives in New York State were the Delta variant; and

WHEREAS certain settings, such as healthcare facilities, pose increased challenges and urgency for controlling the spread of this disease because of the vulnerable patient and resident populations that they serve; and

WHEREAS unvaccinated personnel in such settings have an unacceptably high risk of both acquiring COVID-19 and transmitting such virus to colleagues and/or vulnerable patients or residents; and

WHEREAS based upon the foregoing, the Commissioner of Health of the State of New York is of the Opinion that all entities identified in this Order ("covered entities"), must immediately implement and comply with the requirements identified herein, and that failure to do so constitutes a danger to the health, safety, and welfare of the people of the State of New York; and

WHEREAS the Commissioner of Health of the State of New York has determined that requiring covered entities to immediately implement and comply with the requirements set forth herein and cannot be achieved through alternative means, including the adoption of the Public Health and Health Planning Council of emergency regulations, without delay, which would be prejudicial to health, safety, and welfare of the people of the State of New York; and

WHEREAS it therefore appears to be prejudicial to the interest of the people to delay action for fifteen (15) days until an opportunity for a hearing can be provided in accordance with the provisions of Public Health Law Section (PHL) 12-a.

NOW, THEREFORE, THE HEALTH COMMISSIONER HEREBY ORDERS THAT: Pursuant to PHL § 16:

(a) Definitions.

(1) Covered entity shall mean a general hospital or nursing home pursuant to section 2801 of the Public Health Law.

(2) Covered Personnel. All persons employed or affiliated with a covered entity, whether paid or unpaid, including but not limited to employees, members of the medical and nursing staff, contract staff, students, and volunteers, who engage in activities such that if

they were infected with COVID-19, they could potentially expose, patients, residents, or personnel working for such entity to the disease.

(3) Fully vaccinated. Covered personnel are considered fully vaccinated for COVID-19 ≥ 2 weeks after receiving either (1) the second dose in a 2-dose series (e.g., Pfizer-BioNTech or Moderna), or (2) a single-dose vaccine (e.g., Johnson & Johnson [J&J]/Janssen), authorized for emergency use or approved by the U.S. Food and Drug Administration, and holds an emergency use listing by the World Health Organization.

(4) Documentation of vaccination shall include:

(i) a record prepared and signed by the licensed health practitioner who administered the vaccine, which may include a CDC COVID-19 vaccine card;

(ii) an official record from one of the following, which may be accepted as documentation of immunization without a health practitioner's signature: a foreign nation, NYS Countermeasure Data Management System (CDMS), the NYS Immunization Information System (NYSIIS), City Immunization Registry (CIR), a Department-recognized immunization registry of another state, or an electronic health record system; or

(iii) any other documentation determined acceptable by the Department. Unless otherwise specified by the Department.

(iv) The following elements, unless otherwise specified by the Department: manufacturer, lot number(s), date(s) of vaccination; and vaccinator or vaccine clinic site.

(b) Covered entities shall continuously require all covered personnel to be fully vaccinated against COVID-19, with the first dose for current personnel received by September 27, 2021. Documentation of such vaccination shall be made in personnel records or other appropriate records in accordance with applicable privacy laws, except as set forth in section (c) of this order.

(c) Limited exemptions to vaccination:

1. Medical exemption. If any licensed physician or certified nurse practitioner certifies that immunization with COVID-19 vaccine is detrimental to a specific member of a covered entity's personnel, based upon a specific pre-existing health condition, the requirements of this section relating to COVID-19 immunization shall be subject to a reasonable accommodation of such health condition only until such immunization is found no longer to be detrimental to the health of such member. The nature and duration of the medical exemption must be stated in the personnel employment medical record and must be in accordance with generally accepted medical standards, (see, for example, the recommendations of the Advisory Committee on Immunization Practices of the U.S. Department of Health and Human Services). Covered entities shall document medical exemptions and any reasonable accommodation in personnel records or other appropriate records in accordance with applicable privacy laws by September 27, 2021, and continuously, as needed, thereafter.
2. Religious exemption. Covered entities shall grant a religious exemption for COVID-19 vaccination for covered personnel if they hold a genuine and sincere religious belief contrary to the practice of immunization, subject to a reasonable accommodation by the

employer. Covered entities shall document such exemptions and such reasonable accommodations in personnel records or other appropriate records in accordance with applicable privacy laws by September 27, 2021, and continuously, as needed, thereafter.

(d) Upon the request of the Department, covered entities must report the number and percentage of covered personnel that have been vaccinated against COVID-19 and the number of personnel for which medical or religious exemptions have been granted by covered entities in a manner and format determined by the Department.

(e) Covered entities shall develop and implement a policy and procedure to ensure compliance with the provisions of Order.

(f) The Department may require all covered personnel, whether vaccinated or unvaccinated, to wear acceptable face coverings for the setting in which they work. Covered entities shall supply acceptable face coverings required by this section at no cost to covered personnel.

FURTHER, I DO HEREBY give notice that any entity that receives notice of and is subject to this Order is provided with an opportunity to be heard at 10:00 a.m. on September 2, 2021, via videoconference, to present any proof that failure to implement and comply with the requirements of this Order does not constitute a danger to the health of the people of the State of New York. If any such entity desires to participate in such a hearing, please inform the Department by written notification to **Vaccine.Order.Hearing@health.ny.gov**, New York State Department of Health, Corning Tower, Room 2438, Governor Nelson A. Rockefeller Empire

EXHIBIT B

State Plaza, Albany, New York 12237, within five (5) days of their receipts of this Order. Please include in the notification the email addresses of all individuals who will be representing or testifying for the entity at the hearing so that an invitation to access the hearing remotely can be provided.

DATED: Albany, New York
August 18, 2021

NEW YORK STATE DEPARTMENT OF HEALTH

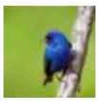
Howard Zucker M.D.

BY: _____
HOWARD A. ZUCKER, M.D., J.D.
Commissioner of Health

EXHIBIT C

EXHIBIT C

Add a comment...



John Gatz

The anti-vaxxers are ignorant trash and don't deserve to live. Gun them down while they're all in one place and let God sort it out

Like · Reply · Mark as spam · 3h

Ez Hsiang

I agree that the anti-vaxxers are messed up and could be a danger to those around them [particularly if those not vaccinated also don't wear masks], but when any of us wish extreme physical harm or death upon those people then we become just as bad as them.

Like · Reply · Mark as spam · 2h

Anthony TJ Weiss

Classy John Gatz. Classy.

Like · Reply · Mark as spam · 1 · 50m

Barbara Kimmel

This is yet another example of scientific ignorance found in Riverhead. Where did these people go to school? High school biology & chemistry detail the critical need for vaccines & masks!

Like · Reply · Mark as spam · 2 · 3h

EXHIBIT D

EXHIBIT D

Bishop Strickland's Letter: Stand for an Ethical Covid-19 Vaccine

by Admin | Dec 8, 2020 | News

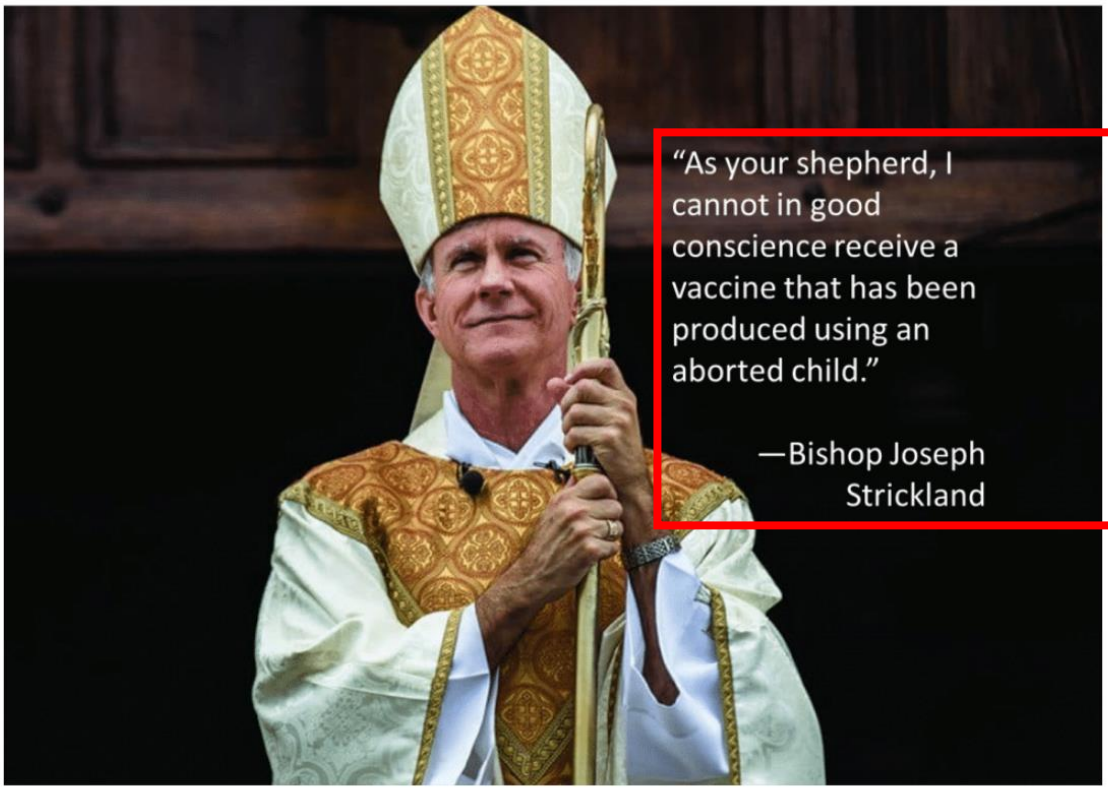


EXHIBIT D

DIOCESE of TYLER

OFFICE OF THE BISHOP

Dear Flock of East Texas,

"*To know that God is not distant but close, not indifferent but compassionate, not aloof but a merciful Father who follows us lovingly with respect for our freedom: all this is a cause of deep joy which the alternating ups and downs of daily life cannot touch*."
Pope John Paul II, Angelus, Third Sunday of Advent, 2003

As the Bishop of the Roman Catholic Diocese of Tyler, I wish you peace as we approach the end of a challenging 2020 and unwavering faith as we enter 2021. We have walked together through these difficult times. Soon we will face the availability of vaccines which we hope will alleviate the painful consequences of COVID-19 and its spread. Along with other Christian leaders, I have stressed the importance of ensuring that vaccines respect the dignity of human life and do *not* use the remains of electively aborted children in any part of the process.

We have the responsibility to make an informed and moral choice as to the use of a particular vaccine. The Church teaches: "Conscience must be informed and moral judgment enlightened. A well-formed conscience is upright and truthful. It formulates its judgments according to reason, in conformity with the true good willed by the wisdom of the Creator" (*Catechism of the Catholic Church* 1783). Christians are called to form their consciences in accordance with what is true as revealed in natural law and divine revelation and to act accordingly when deciding about the use of a COVID-19 vaccine.

Every procured abortion murders an innocent human person. For university, government, or industrial scientists to use materials obtained from the remains of an electively aborted child in the research, development, testing, or production of any vaccine is immoral and constitutes formal cooperation in evil. We must never cease to protest this practice with maximum determination to defend the dignity and sacredness of children in the womb. They are not objects to be used but persons to be received as gifts, our brothers and sisters. As your shepherd, I cannot in good conscience receive a vaccine that has been produced using an aborted child. There are ethical vaccines in development which are worth waiting for.

The instructions, which were promulgated in *Dignitas Personae* in 2008, say we have a duty to ask healthcare systems to do better. In this time of Covid-19, Catholic leaders have not asked for better. Too many have accepted the exploitation of aborted children. I urge you to reject any vaccine that uses the remains of aborted children in research, testing, development, or production. Testify to the truth that abortion must be rejected and make a choice that is consistent with the dignity of every human life from conception to natural death and is rooted in a mature faith and trust in eternal life, not fear of suffering in this life.

EXHIBIT D

DIOCESE of TYLER

OFFICE OF THE BISHOP

As bishop, I affirm the call from the American Association of Pro-Life Obstetricians and Gynecologists, American College of Pediatricians, Catholic Medical Association, and Christian Medical and Dental Associations that we should all "expect and demand vaccines that are safe, effective, and ethically sound" (Joint Statement, December 2, 2020). Until that day, I urge all of us to exercise patience and to educate our conscience by studying the teaching of the Church. Then remain faithful to the truth concerning the dignity of every human life. We must prayerfully consider how we might best conform our will to Jesus Christ and seek the good in all things for ourselves, for our families, and for our communities. To echo *Dignitas Personae*, may we here in East Texas "*mobilize our consciences in favour of life*."

Most Reverend Joseph E. Strickland
Bishop of Tyler

EXHIBIT D

On The Moral Illicitness Of The Use Of Vaccines Made From Cells Derived From Aborted Human Fetuses

In recent weeks, news agencies and various information sources have reported that, in response to the Covid-19 emergency, some countries have produced vaccines using cell lines from aborted human fetuses. In other countries, such vaccines are being planned.

A growing chorus of churchmen (bishops' conferences, individual bishops, and priests) has said that, in the event that no alternative vaccine using ethically licit substances is available, it would be morally permissible for Catholics to receive vaccines made from the cell lines of aborted babies. Supporters of this position invoke two documents of the Holy See: the first, from the Pontifical Academy for Life, is titled, "Moral reflections on vaccines prepared from cells derived from aborted human fetuses" and was issued on June 9, 2005; the second, an Instruction from the Congregation for the Doctrine of the Faith, is titled, *"Dignitas Personae, on certain bioethical questions*" and was issued on September 8, 2008. Both of these documents allow for the use of such vaccines in exceptional cases and for a limited time, on the basis of what in moral theology is called *remote, passive, material cooperation* with evil. The aforementioned documents assert that Catholics who use such vaccines at the same time have "the duty to make known their disagreement and to ask that their healthcare system make other types of vaccines available."

In the case of vaccines made from the cell lines of aborted human fetuses, we see a clear contradiction between the Catholic doctrine to categorically, and beyond the shadow of any doubt, reject abortion in all cases as a grave moral evil that cries out to heaven for vengeance (see *Catechism of the Catholic Church* n. 2268, n. 2270), and the practice of regarding vaccines derived from aborted fetal cell lines as morally acceptable in exceptional cases of "urgent need" — on the grounds of remote, passive, material cooperation. To argue that such vaccines can be morally licit if there is no alternative is in itself contradictory and cannot be acceptable for Catholics.

One ought to recall the following words of Pope John Paul II regarding the dignity of unborn human life: "The inviolability of the person which is a reflection of the absolute inviolability of God, finds its primary and fundamental expression in the inviolability of human life. Above all, the common outcry, which is justly made on behalf of human rights — for example, the right to health, to home, to work, to family, to culture — is false and illusory if the right to life, the most basic and fundamental right and the condition for all other personal rights, is not defended with maximum determination." (*Christifideles Laici*, 38). Using vaccines made from the cells of murdered unborn children contradicts a "maximum determination" to defend unborn life.

The theological principle of *material cooperation* is certainly valid and may be applied to a whole host of cases (e.g. in paying taxes, the use of products made from slave labor, and so on). However, this principle can hardly be applied to the case of vaccines made from fetal cell lines, because those who knowingly and voluntarily receive such vaccines enter into a kind of concatenation, albeit very remote, with the process of the abortion industry. The crime of abortion is so monstrous that any kind of concatenation with this crime, even a very remote one, is immoral and cannot be accepted under any

circumstances by a Catholic once he has become fully aware of it. One who uses these vaccines must realize that his body is benefitting from the "fruits" (although steps removed through a series of chemical processes) of one of mankind's greatest crimes.

Any link to the abortion process, even the most remote and implicit, will cast a shadow over the Church's duty to bear unwavering witness to the truth that abortion must be utterly rejected. The ends cannot justify the means. We are living through one of the worst genocides known to man. Millions upon millions of babies across the world have been slaughtered in their mother's womb, and day after day this hidden genocide continues through the abortion industry, biomedical research and fetal technology, and a push by governments and international bodies to promote such vaccines as one of their goals. Now is not the time for Catholics to yield; to do so would be grossly irresponsible. The acceptance of these vaccines by Catholics, on the grounds that they involve only a "remote, passive and material cooperation" with evil, would play into the hands of the Church's enemies and weaken her as the last stronghold against the evil of abortion.

What else can a vaccine derived from fetal cell lines be other than a violation of the God-given Order of Creation? For it is based on a serious violation of this Order through the murder of an unborn child. Had this child not been denied the right to life, had his cells (which have been further cultivated several times in the lab) not been made available for the production of a vaccine, they could not be marketed. We therefore have here a double violation of God's holy Order: on the one hand, through the abortion itself, and on the other hand, through the heinous business of trafficking and marketing the remains of aborted children. Yet, this double disregard for the divine Order of Creation can never be justified, not even on the grounds of preserving the health of a person or society through such vaccines. Our society has created a substitute religion: health has been made the highest good, a substitute god to whom sacrifices must be offered — in this case, through a vaccine based on the death of another human life.

In examining the ethical questions surrounding vaccines, we have to ask ourselves: How and why did all of this become possible? Was there truly no alternative? Why did murder-based technology emerge in medicine, whose purpose is instead to bring life and health? Bio-medical research that exploits the innocent unborn and uses their bodies as "raw material" for the purpose of vaccines seems more akin to cannibalism than medicine. We also ought to consider that, for some in the bio-medical industry, the cell lines of unborn children are a "product," the abortionist and vaccine manufacturer are the "supplier," and the recipients of the vaccine are "consumers." Technology based on murder is rooted in hopelessness and ends in despair. We must resist the myth that "there is no alternative." On the contrary, we must proceed with the hope and conviction that alternatives exist, and that human ingenuity, with the help of God, can discover them. This is the only way to pass from darkness to light, and from death to life.

The Lord said that in the end times even the elect will be seduced (cf. Mk. 13:22). Today, the entire Church and all Catholic faithful must urgently seek to be strengthened in the doctrine and practice of the faith. In confronting the evil of abortion, more than ever Catholics must "abstain from all appearance of evil" (1 Thess. 5:22). Bodily health is not an absolute value. Obedience to the law of God and the eternal salvation of the souls must be given primacy. Vaccines derived from the cells of cruelly murdered unborn

children are clearly apocalyptic in character and may possibly foreshadow the mark of the beast (see Rev. 13:16).

Some churchmen in our day reassure the faithful by affirming that receiving a Covid-19 vaccine derived from the cell lines of an aborted child is morally licit if an alternative is not available. They justify their assertion on the basis of "material and remote cooperation" with evil. Such affirmations are extremely anti-pastoral and counterproductive, especially when one considers the increasingly apocalyptic character of the abortion industry, and the inhuman nature of some biomedical research and embryonic technology. Now more than ever, Catholics categorically cannot encourage and promote the sin of abortion, even in the slightest, by accepting these vaccines. Therefore, as Successors of the Apostles and Shepherds responsible for the eternal salvation of souls, we consider it impossible to be silent and maintain an ambiguous attitude regarding our duty to resist with "maximum of determination" (Pope John Paul II) against the "unspeakable crime" of abortion (II Vatican Council, *Gaudium et Spes*, 51).

This statement was written at the advice and counsel of doctors and scientists from various countries. A substantial contribution also came from the laity: from grandmothers, grandfathers, fathers and mothers of families, and from young people. All of those consulted — independent of age, nationality and profession — unanimously and almost instinctively rejected the idea of a vaccine derived from the cell lines of aborted children. Furthermore, they considered the justification offered for using such vaccines (i.e. "material remote cooperation") as weak and unsuitable. This is comforting and, at the same time, very revealing: their unanimous response is a further demonstration of the strength of reason and the *sensus fidei*.

More than ever, we need the spirit of the confessors and martyrs who avoided the slightest suspicion of collaboration with the evil of their own age. The Word of God says: "Be simple as children of God without reproach in the midst of a depraved and perverse generation, in which you must shine like lights in the world" (Phil. 2, 15).

December 12, 2020, Memorial of the Blessed Virgin Mary of Guadalupe

Cardinal Janis Pujats, Metropolitan archbishop emeritus of Riga

+ Tomash Peta, Metropolitan archbishop of the archdiocese of Saint Mary in Astana

+ Jan Pawel Lenga, Archbishop/bishop emeritus of Karaganda

+ Joseph E. Strickland, Bishop of Tyler (USA)

+ Athanasius Schneider, Auxiliary bishop of the archdiocese of Saint Mary in Astana

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Statement of Conscience

To Awaken Conscience

Share Tweet

"Abortion has become the greatest destroyer of peace, because it destroys two lives, the life of the child and the conscience of the mother."
Mother Teresa of Calcutta (1988)

"She is the human and sacred image; all around her the social fabric shall sway and split and fall; the pillars of society shall be shaken, and the roofs of ages come rushing down, and not one hair of her head shall be harmed."
G.K. Chesterton, What's Wrong with the World

We the undersigned, men and women in solidarity with the weakest among us, wish to respond publicly to what appears to be a growing consensus among Catholic ethicists that vaccines derived from aborted fetal tissue are not only morally permissible (licit), but also (*nearly*) *morally obligatory* for the sake of the common good. Examples include, among others, this statement organized by EPPC, the steady position of the Catholic Health Association (CHA), and a December statement of the USCCB which says that receiving the (abortion-tainted) COVID-19 vaccine "should be considered...part of our moral responsibility for the common good." These statements are troubling to us, and seem to run afoul of our rights of conscience to refuse such vaccines, clearly defended by the Church, in *Dignitas Personae* (CDF 2008) and *Note on the morality of using some Covid-19 vaccines* (CDF 2020). We now fear the circling of the wagons around abortion-tainted vaccines, advanced by powerful voices which seem ready to silence our moral intuitions.

We resist this "consensus" being foisted upon us as morally repugnant: we do not wish to benefit from abortion. We deplore the lack of moral imagination displayed by public health officials, politicians, and all those who disregard the natural disgust felt by persons who wish to remain separate from the crime of abortion in every way possible. And we lament a "soulless scientism" that fails to account for the unique dignity of the human person and the role of suffering in human life.

We are puzzled and pained by the lack of reasonable skepticism which pro-life persons ought to show for

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the scientific-industrial complex (SIC). A distortion of medical and scientific standards so often accompanies questionable ethical practices, and a "science" which denies life inevitably takes life. Consequently, there are many reasons why a person may feel duty-bound to avoid these vaccines besides religious conviction, such as the experimental nature of them (FDA "emergency use") and the unknown effects, especially on children and pregnant women.

We hereby urge, by our witness and testimony, that people who agree with us—and also those who disagree but who admire our stance, and who wish to defend our right to hold it—join together to claim the freedom in conscience to refuse vaccines derived from aborted fetal cell lines.

"There is a grave responsibility to use alternative vaccines and to make a conscientious objection with regard to those which have moral problems," wrote the Pontifical Academy for Life in 2005, in guidance confirmed by the Congregation for the Doctrine of the Faith; abortion-tainted vaccines create a "context of moral coercion of the conscience of parents, who are forced to choose to act against their conscience." Indeed, many of us have spent decades trying to resist the abortion-tainted varicella and MMR vaccines, which were produced in the same compromised way, meeting resistance everywhere, being 'fired' by our physicians, and opposed even by leaders of our own churches. Many Catholic schools even *require* students to obtain the morally objectionable vaccines in order to attend.

These failures make us now question whether earlier capitulations (on the grounds that there was 'no alternative') were the right courses of action. The threats grow by the moment. Even now, there is pending legislation which would allow children the right to consent to vaccines *without parental knowledge*. Such a policy has implications far beyond the present crisis. We wish to call attention to the unintended consequences of a 'soft opposition' of words and not of deeds. Coercion in these and other matters hostile to life is coming.

We are told there is nearly ubiquitous use of HEK-293 cells in the scientific and medical industry. If this is so, we take it to be evidence of structures of sin surrounding abortion. We invite (and call upon our lawmakers to require) all product manufacturers to reveal publicly and label their use of these cells, so that we can go forward avoiding such products. More has been done to resist animal cruelty and the use of genetically modified organisms than to resist the benefiting from the murder of a child. (The very same papers which report tests of vaccines using HEK-293 cells take pains in their disclosures to say that no animals were mistreated in the course of their research!) We lament that we have been led to use compromised products and medicines in the past without knowledge. Let all that has been hidden be brought into the light.

We find insufficient the accounts of moralists who lean on casuistical distinctions, originally designed to analyze private action in a Christian society, when we are crushed by a public edifice determined to protect the so-called 'right to abortion', and determined in addition to benefit from its byproducts in many ways beyond the current (and previous) vaccines. We know that trafficking in aborted fetal body parts exists and amounts to an industry. The acceptance of the use of tissues derived in the past does have implications for incentivizing this industry. While no attention is given to the truth about human life in the

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public square, and while academia, the media, and elite institutions remain in the grips of a "culture of death," we believe a more radical public witness is needed today.

We remember the holy mother in 2 Maccabees, a type of Our Lady, who urged her sons to resist violating God's law even if it meant their death, saying, "Therefore the Creator of the world, who shaped the beginning of man and devised the origin of all things, will in his mercy give life and breath back to you again, since you now forget yourselves for the sake of his laws." We expect great public good to arise if her example of witness to higher goods and God's sovereignty inspires our actions today. The march of science, the treatments it pursues, the political incentives it responds to, none of them are immune from moral witness. Without our courage we fear that pinches of incense will continue to be extracted from us, rendering us insensitive to what should cause our indignation, sorrow, and determination to change.

The abortions from which the cell lines are derived are said to be so "remote" as to be like roads constructed by slave laborers hundreds of years ago. Surely remoteness is a judgment in conscience. How "remote" is a cell line connected by continuous life with the murdered child? How "remotely" long ago is the abortion of a child who would be only 50 years old today? It is urged, as if it mattered, that the abortions were not carried out *in order to* create the cell lines—and yet the tissue of the aborted child (which no lab scientist had authority to use) did not miraculously give rise to cell lines but instead was manipulated deliberately, precisely in order to create the cell lines. Therefore, the use of these cell lines exactly corresponds to and complements the depraved intention to create them.

"Protect unborn man from born man!" St. John Paul II exhorted us. We live in a world divided into a Way of Life and a Way of Death. The Way of Death is this: born man subordinates unborn man to himself, for his own advantage. The Way of Life is this: born man unwaveringly and resolutely protects unborn man, even to his own disadvantage. To which culture do we wish to belong? With which do we identify? "What does it profit a man to gain his life but lose his soul?"

We therefore urge our ethicists to resist a premature "consensus" about abortion-tainted SARS-CoV-2 vaccines. We insist on our freedom of conscience in this matter, to witness to life as we judge we are being called to do. We also urge a reconsideration of earlier "consensus" views about previous abortion-tainted

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vaccines. And we urge a public reckoning as regards every secret use of these cells derived from an abortion.

We reiterate in closing: even if, as a matter of general principles, it is not always morally illicit to use such abortion-tainted vaccines temporarily, in extreme necessity, and even then under strenuous protest, the use of such vaccines must never be advanced as mandatory, or as a universal duty. Because some of us in conscience believe that we are called to refuse to take them.

St. Gianna Beretta Molla, pray for us!

Signed by,

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Bishop of Tyler
Tyler, TX

Over 7,000 Signatories

Click here to see list of signatories.

We invite you to join us, and add your signature below.

If you believe that we should have space in conscience to refuse the vaccine on ethical grounds, you

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are invited to sign this statement too. **Note:** by signing you consent for your name and location to be publicly displayed and shared with Church and government leaders. A signature does not mean that you affirm every word in the statement but that you want to stand with us in the defense of freedom of conscience.

Email Address

First Name

Last Name

Organization (Optional)

City, State (or Country)

Sign the Statement

Share Tweet

#resistabortionbenefit

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[DE - EN - ES - FR - IT - PT]

CONGREGATION FOR THE DOCTRINE OF THE FAITH

Note on the morality of using some anti-Covid-19 vaccines

The question of the use of vaccines, in general, is often at the center of controversy in the forum of public opinion. In recent months, this Congregation has received several requests for guidance regarding the use of vaccines against the SARS-CoV-2 virus that causes Covid-19, which, in the course of research and production, employed cell lines drawn from tissue obtained from two abortions that occurred in the last century. At the same time, diverse and sometimes conflicting pronouncements in the mass media by bishops, Catholic associations, and experts have raised questions about the morality of the use of these vaccines.

There is already an important pronouncement of the Pontifical Academy for Life on this issue, entitled "Moral reflections on vaccines prepared from cells derived from aborted human fetuses" (5 June 2005). Further, this Congregation expressed itself on the matter with the Instruction *Dignitas Personae* (September 8, 2008, cf. nn. 34 and 35). In 2017, the Pontifical Academy for Life returned to the topic with a Note. These documents already offer some general directive criteria.

Since the first vaccines against Covid-19 are already available for distribution and administration in various countries, this Congregation desires to offer some indications for clarification of this matter. We do not intend to judge the safety and efficacy of these vaccines, although ethically relevant and necessary, as this evaluation is the responsibility of biomedical researchers and drug agencies. Here, our objective is only to consider the moral aspects of the use of the vaccines against Covid-19 that have been developed from cell lines derived from tissues obtained from two fetuses that were not spontaneously aborted.

1. As the Instruction *Dignitas Personae* states, in cases where cells from aborted fetuses are employed to create cell lines for use in scientific research, "there exist differing degrees of responsibility"[1] of cooperation in evil. For example,"in organizations where cell lines of illicit origin are being utilized, the responsibility of those who make the decision to use them is not the same as that of those who have no voice in such a decision".[2]

2. In this sense, when ethically irreproachable Covid-19 vaccines are not available (e.g. in countries where vaccines without ethical problems are not made available to physicians and patients, or where their distribution is more difficult due to special storage and transport conditions, or when various types of vaccines are distributed in the same country but health authorities do not allow citizens to choose the vaccine with which to be inoculated) *it is morally acceptable to receive Covid-19 vaccines that have used cell lines from aborted fetuses in their research and production process.*

3. The fundamental reason for considering the use of these vaccines morally licit is that the kind of

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cooperation in evil (*passive material cooperation*) in the procured abortion from which these cell lines originate is, on the part of those making use of the resulting vaccines, *remote*. The moral duty to avoid such passive material cooperation is not obligatory if there is a grave danger, such as the otherwise uncontainable spread of a serious pathological agent[3]--in this case, the pandemic spread of the SARS-CoV-2 virus that causes Covid-19. It must therefore be considered that, in such a case, all vaccinations recognized as clinically safe and effective can be used in good conscience with *the certain knowledge that the use of such vaccines does not constitute formal cooperation with the abortion* from which the cells used in production of the vaccines derive. It should be emphasized, however, that the morally licit use of these types of vaccines, in the particular conditions that make it so, does not in itself constitute a legitimation, even indirect, of the practice of abortion, and necessarily assumes the opposition to this practice by those who make use of these vaccines.

4. In fact, the licit use of such vaccines does not and should not in any way imply that there is a moral endorsement of the use of cell lines proceeding from aborted fetuses.[4] Both pharmaceutical companies and governmental health agencies are therefore encouraged *to produce, approve, distribute and offer ethically acceptable vaccines that do not create problems of conscience* for either health care providers or the people to be vaccinated.

5. At the same time, practical reason makes evident that vaccination is not, as a rule, a moral obligation and that, therefore, it must be voluntary. In any case, from the ethical point of view, *the morality of vaccination depends not only on the duty to protect one's own health, but also on the duty to pursue the common good.* In the absence of other means to stop or even prevent the epidemic, the common good may recommend vaccination, especially to protect the weakest and most exposed. Those who, however, for reasons of conscience, refuse vaccines produced with cell lines from aborted fetuses, must do their utmost to avoid, by other prophylactic means and appropriate behavior, becoming vehicles for the transmission of the infectious agent. In particular, they must avoid any risk to the health of those who cannot be vaccinated for medical or other reasons, and who are the most vulnerable.

6. Finally, there is also a moral imperative for the pharmaceutical industry, governments and international organizations *to ensure that vaccines, which are effective and safe from a medical point of view, as well as ethically acceptable, are also accessible to the poorest countries in a manner that is not costly for them.* The lack of access to vaccines, otherwise, would become another sign of discrimination and injustice that condemns poor countries to continue living in health, economic and social poverty.[5]

The Sovereign Pontiff Francis, at the Audience granted to the undersigned Prefect of the Congregation for the Doctrine of the Faith, on 17 December 2020, examined the present Note and ordered its publication.

Rome, from the Offices of the Congregation for the Doctrine of the Faith, on 21 December 2020, Liturgical Memorial of Saint Peter Canisius.

Luis F. Card. Ladaria, S.I.
Prefect

+ S.E. Mons. Giacomo Morandi
Titular Archbishop of Cerveteri
Secretary

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[1] Congregation for the Doctrine of the Faith, Instruction *Dignitas Personae* (8 th December 2008), n.

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35; *AAS* (100), 884.

[2] *Ibid*, 885.

[3] Cfr. Pontifical Academy for Life, "Moral reflections on vaccines prepared from cells derived from aborted human foetuses", 5th June 2005.

[4] Congregation for the Doctrine of the Faith, Instruct. *Dignitas Personae*, n. 35: "When the illicit action is endorsed by the laws which regulate healthcare and scientific research, it is necessary to distance oneself from the evil aspects of that system in order not to give the impression of a certain toleration or tacit acceptance of actions which are gravely unjust. Any appearance of acceptance would in fact contribute to the growing indifference to, if not the approval of, such actions in certain medical and political circles".

[5] Cfr. Francis, *Address to the members of the "Banco Farmaceutico" foundation*, 19 September 2020.

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COVID-19

- Get the latest public health information from CDC
- NIH staff guidance on coronavirus (NIH Only)
- Get the latest research information from NIH | Español

NIH RESEARCH MATTERS

January 26, 2021

Lasting immunity found after recovery from COVID-19

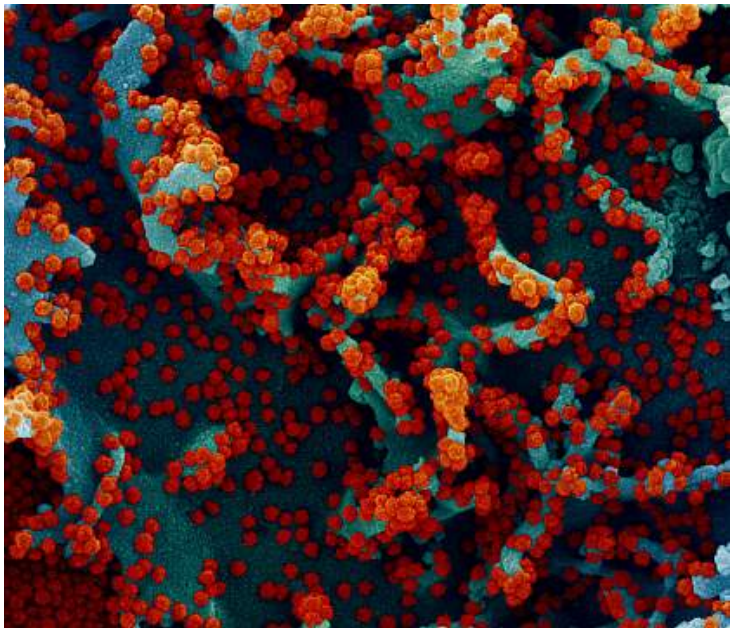
At a Glance

- The immune systems of more than 95% of people who recovered from COVID-19 had durable memories of the virus up to eight months after infection.
- The results provide hope that people receiving SARS-CoV-2 vaccines will develop similar lasting immune memories after vaccination.

After people recover from infection with a virus, the immune system retains a memory of it. Immune cells and proteins that circulate in the body can recognize and kill the pathogen if it's encountered again, protecting against disease and reducing illness severity.

This long-term immune protection involves several components. Antibodies—proteins that circulate in the blood—recognize foreign substances like viruses and neutralize them. Different types of T cells help recognize and kill pathogens. B cells make new antibodies when the body needs them.

All of these immune-system components have been found in people who recover from SARS-CoV-2, the virus that causes COVID-19. But the details of this immune response and how long it lasts after infection have been unclear. Scattered reports of reinfection with SARS-CoV-2 have raised concerns that the immune response to the virus might not be durable.



Colorized scanning electron micrograph of a cell, isolated from a patient sample, that is heavily infected with SARS-CoV-2 virus particles (red).
NIAID Integrated Research Facility, Fort Detrick, Maryland

To better understand immune memory of SARS-CoV-2, researchers led by Drs. Daniela Weiskopf, Alessandro Sette, and Shane Crotty from the La Jolla Institute for Immunology analyzed immune cells and antibodies from almost 200 people who had been exposed to SARS-CoV-2 and recovered.

Time since infection ranged from six days after symptom onset to eight months later. More than 40 participants had been recovered for more than six months before the study began. About 50 people provided blood samples at more than one time after infection.

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The research was funded in part by NIH's National Institute of Allergy and Infectious Diseases (NIAID) and National Cancer Institute (NCI). Results were published on January 6, 2021, in *Science*.

The researchers found durable immune responses in the majority of people studied. Antibodies against the spike protein of SARS-CoV-2, which the virus uses to get inside cells, were found in 98% of participants one month after symptom onset. As seen in previous studies, the number of antibodies ranged widely between individuals. But, promisingly, their levels remained fairly stable over time, declining only modestly at 6 to 8 months after infection.

Virus-specific B cells increased over time. People had more memory B cells six months after symptom onset than at one month afterwards. Although the number of these cells appeared to reach a plateau after a few months, levels didn't decline over the period studied.

Levels of T cells for the virus also remained high after infection. Six months after symptom onset, 92% of participants had CD4+ T cells that recognized the virus. These cells help coordinate the immune response. About half the participants had CD8+ T cells, which kill cells that are infected by the virus.

As with antibodies, the numbers of different immune cell types varied substantially between individuals. Neither gender nor differences in disease severity could account for this variability. However, 95% of the people had at least 3 out of 5 immune-system components that could recognize SARS-CoV-2 up to 8 months after infection.

"Several months ago, our studies showed that natural infection induced a strong response, and this study now shows that the responses last," Weiskopf says. "We are hopeful that a similar pattern of responses lasting over time will also emerge for the vaccine-induced responses."

—by Sharon Reynolds

Related Links

- Experimental Coronavirus Vaccine Highly Effective (https://www.nih.gov/news-events/nih-research-matters/experimental-coronavirus-vaccine-highly-effective)
- Antibodies and T Cells Protect Against SARS-CoV-2 (https://www.nih.gov/news-events/nih-research-matters/antibodies-t-cells-protect-against-sars-cov-2)
- Immune Cells for Common Cold May Recognize SARS-CoV-2 (https://www.nih.gov/news-events/nih-research-matters/immune-cells-common-cold-may-recognize-sars-cov-2)
- Potent Neutralizing Antibodies Target New Regions of Coronavirus Spike (https://www.nih.gov/news-events/nih-research-matters/potent-neutralizing-antibodies-target-new-regions-coronavirus-spike)
- Potent Antibodies Found in People Recovered from COVID-19 (https://www.nih.gov/news-events/nih-research-matters/potent-antibodies-found-people-recovered-covid-19)
- Novel Coronavirus Structure Reveals Targets for Vaccines and Treatments (https://www.nih.gov/news-events/nih-research-matters/novel-coronavirus-structure-reveals-targets-vaccines-treatments)
- Coronavirus (COVID-19) (https://covid19.nih.gov/)
- Coronavirus Prevention Network (https://www.coronaviruspreventionnetwork.org/)
- Coronavirus (COVID-19) (https://www.coronavirus.gov/)

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Funding: NIH's National Institute of Allergy and Infectious Diseases (NIAID) and National Cancer Institute (NCI); La Jolla Institute for Immunology; John and Mary Tu Foundation; Bill and Melinda Gates Foundation; Mastercard; Wellcome; Emergent Ventures; Collaborative Influenza Vaccine Innovation Centers; JPB Foundation; Cohen Foundation; Open Philanthropy Project.

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15 Studies That Indicate Natural Immunity From Prior Infection Is More Robust Than The COVID Vaccines:

SOURCE: Daniel Horowitz: *15 studies that indicate natural immunity from prior infection is more robust than the COVID vaccines*

[….]

1) New York University, May 3, 2021

The authors studied the contrast between vaccine immunity and immunity from prior infection as it relates to stimulating the innate T-cell immunity, which is more durable than adaptive immunity through antibodies alone. They concluded, "In COVID-19 patients, immune responses were characterized by a highly augmented interferon response which was largely absent in vaccine recipients. Increased interferon signaling likely contributed to the observed dramatic upregulation of cytotoxic genes in the peripheral T cells and innate-like lymphocytes in patients but not in immunized subjects."

The study further notes: "Analysis of B and T cell receptor repertoires revealed that while the majority of clonal B and T cells in COVID-19 patients were effector cells, in vaccine recipients clonally expanded cells were primarily circulating memory cells." What this means in plain English is that effector cells trigger an innate response that is quicker and more durable, whereas memory response requires an adaptive mode that is slower to respond. Natural immunity conveys much more innate immunity, while the vaccine mainly stimulates adaptive immunity.

2) Washington University, St. Louis, Missouri, May 24, 2021, published in Nature

The media scared people last year into thinking that if antibody levels wane, it means their immunity is weakening, as we are indeed seeing with the vaccines today. But as Nature wrote, "People who recover [even] from mild COVID-19 have bone-marrow cells that can churn out antibodies for decades." Thus, aside from the robust T-cell memory that is likely lacking from most or all vaccinated individuals, prior infection creates memory B cells that "patrol the blood for reinfection, while bone marrow plasma cells (BMPCs) hide away in bones, trickling out antibodies for decades" as needed.

It's therefore not surprising that early on in the pandemic, an in-vitro study in Singapore found the immunity against SARS-CoV-2 to last even 17 years later from SARS-1-infected patients who never even had COVID-19.

3) Cleveland Clinic, June 19, 2021

In a study of 1,359 previously infected health care workers in the Cleveland Clinic system, not a single one of them was reinfected 10 months into the pandemic, despite some of these individuals being around COVID-positive patients more than the regular population.

4) Fred Hutchinson Cancer Research Center, Seattle/Emory University, Washington, July 14, 2021, published in Cell Medicine

The study found that most recovered patients produced durable antibodies, memory B cells, and durable polyfunctional CD4 and CD8 T cells, which target multiple parts of the virus. "Taken together, these results suggest that broad and effective immunity may persist long-term in recovered COVID-19 patients," concluded the authors. In other words, unlike with the vaccines, no boosters are required to assist natural immunity.

5) University of California, Irvine, July 21, 2021

The authors conclude: "Natural infection induced expansion of *larger* CD8 T cell clones occupied distinct clusters, likely due to the *recognition of a broader set of viral epitopes* presented by the virus *not seen in the mRNA vaccine*" (emphasis added).

6) University of California, San Francisco, May 12, 2021

Conclusion: "In infection-naïve individuals, the second dose boosted the quantity but not quality of the T cell response, while in convalescents the second dose helped neither. Spike-specific T cells from convalescent vaccinees differed strikingly from those of infection-naïve vaccinees, with phenotypic features suggesting superior long-term persistence and ability to home to the respiratory tract including the nasopharynx."

Given that we know the virus spreads through the nasopharynx, the fact that natural infection conveys much stronger mucosal immunity makes it clear that the previously infected are much safer to be around than infection-naive people with the vaccine. The fact that this study artfully couched the choices between vaccinated naive people and vaccinated recovered rather than just plain recovered doesn't change the fact that it's the prior infection, not the vaccine, conveying mucosal immunity. In fact, studies now show that infected vaccinated people contain just as much viral load in their nasopharynx as those unvaccinated, a clearly unmistakable conclusion from the virus spreading wildly in many areas with nearly every adult vaccinated.

7) Israeli researchers, August 22, 2021

Aside from more robust T cell and memory B cell immunity, which is more important than antibody levels, Israeli researchers found that antibodies wane slower among those with prior infection. "In vaccinated subjects, antibody titers decreased by up to 40% each subsequent month while in convalescents they decreased by less than 5% per month."

8) Irish researchers, published in Wiley Review, May 18, 2021

Researchers conducted a review of 11 cohort studies with over 600,000 total recovered COVID patients who were followed up with over 10 months. The key finding? Unlike the vaccine, after about four to six months, they found "no study reporting an increase in the risk of reinfection over time."

9) Cornell University, Doha, Qatar, published in the Lancet, April 27, 2021

This is one of the only studies that analyzed the population-level risk of reinfection based on whole genome sequencing in a subset of patients with supporting evidence of reinfection. Researchers estimate the risk at 0.66 per 10,000 person-weeks. Most importantly, the study found no evidence of waning of immunity for over seven months of the follow-up period. The few reinfections that did occur "were less severe than primary infections," and "only one reinfection was severe, two were moderate, and none were critical or fatal." Also, unlike many vaccinated breakthrough infections in recent weeks that have been very symptomatic, "most reinfections were diagnosed incidentally through random or routine testing, or through contact tracing."

10) Israeli researchers, April 24, 2021

Several months ago, Israeli researchers studied 6.3 million Israelis and their COVID status and were able to confirm only one death in the entire country of someone who supposedly already had the virus, and he was over 80 years old. Contrast that to the torrent of hospitalizations and deaths we are seeing in those vaccinated more than five months ago in Israel.

11) French researchers, May 11, 2021

Researchers tested blood samples from health care workers who never had the virus but got both Pfizer shots against blood samples from those health care workers who had a previous mild infection and a third group of patients who had a serious case of COVID. They found, "No neutralization escape could be feared concerning the two variants of concern [Alpha and Beta] in both populations" of those previously infected.

12) Duke-NUS Medical School, Singapore, published in Journal of Experimental Medicine

Many people are wondering: If they got only an asymptomatic infection, are they less protected against future infection than those who suffered infection with more evident symptoms? These researchers believe the opposite is true. "Asymptomatic SARS-CoV-2–infected individuals are not characterized by weak antiviral immunity; on the contrary, they mount a highly functional virus-specific cellular immune response," wrote the authors after studying T cell responses from both symptomatic and asymptomatic convalescent patients. If anything, they found that those with asymptomatic infection only had signs of non-inflammatory cytokines, which means that the body is primed to deal with the virus without producing that dangerous inflammatory response that is killing so many hospitalized with the virus.

13) Korean researchers, published in Nature Communications on June 30, 2021

The authors found that the T cells created from convalescent patients had "stem-cell like" qualities. After studying SARS-CoV-2-specific memory T cells in recovered patients who had the virus in varying degrees of severity, the authors concluded that long-term "SARS-CoV-2-specific T cell memory is successfully maintained regardless of the severity of COVID-19."

14) Rockefeller University, July 29, 2021

The researchers note that far from suffering waning immunity, memory B cells in those with prior infection "express increasingly broad and potent antibodies that are resistant to mutations found in variants of concern." They conclude that "memory antibodies selected over time by natural infection have greater potency and breadth than antibodies elicited by vaccination." And again, this is even before getting into the innate cellular immunity which is exponentially greater in those with natural immunity.

15) Researchers from Madrid and Mount Sinai, New York, March 22, 2021

Until now, we have established that natural immunity provides better adaptive B cell and innate T cell responses that last longer and work for the variants as compared to the vaccines. Moreover, those with prior infection are at greater risk for bad side effects from the vaccines, rendering the campaign to vaccinate the previously infected both unnecessary and dangerous. But the final question is: Do the vaccines possibly *harm* the superior T cell immunity built up from prior infection?

* Vaccinations appear to have detrimental impact on pre-existing immunity

Immunologists from Mount Sinai in New York and Hospital La Paz in Madrid have raised serious concerns. In a shocking discovery after monitoring a group of vaccinated people both with and without prior infection, they found "in individuals with a pre-existing immunity against SARS-CoV-2, the second vaccine dose not only fail to boost humoral immunity but determines a contraction of the spike-specific T cell response." They also note that other research has shown "the second vaccination dose appears to exert a detrimental effect in the overall magnitude of the spike-specific humoral response in COVID-19 recovered individuals."

As early as March 27, among the many accurate statements Dr. Fauci made before he became a political animal, he declared he was "really confident" in the immunity conferred by prior infection. That was long before 17 months of data and dozens of studies confirmed that. Yet, today, there are thousands of doctors and nurses with infinitely better immunity than what the vaccines can confer who are losing their jobs during a staffing crisis for not getting the shots. Just know that the big lie about natural immunity is perhaps the most verifiable lie, but it is likely not the only lie with devastating consequences we are being told about the virus, the vaccines, and alternative treatment options.

FEE Stories

Harvard Epidemiologist Says the Case for COVID Vaccine Passports Was Just Demolished

New research found that natural immunity offers exponentially more protection than COVID-19 vaccines.

Monday, August 30, 2021

Photo by Thérèse Soukar, CC BY-SA 4.0 , via Wikimedia Commons

Jon Miltimore

Politics Vaccine Passport Vaccines Natural Immunity COVID-19

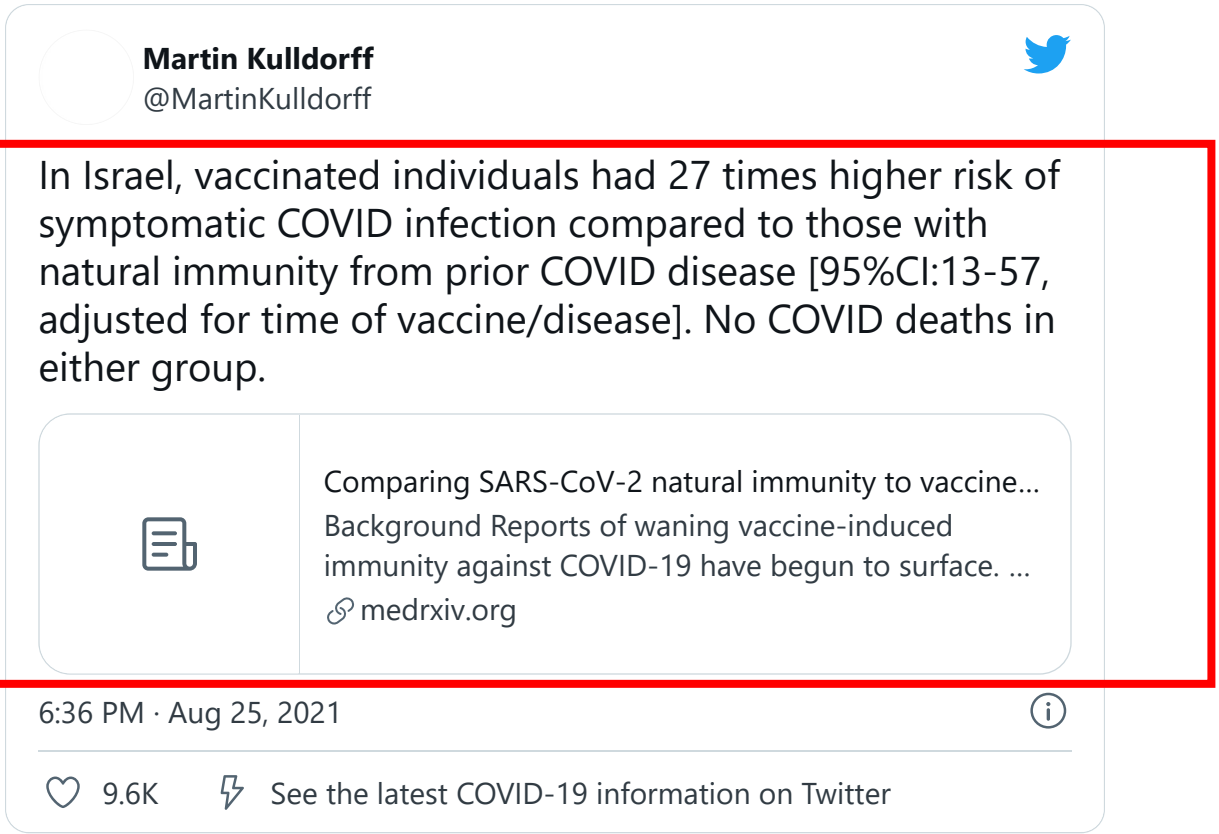
Freedom of Movement CDC Israel

A newly published medical study found that infection from COVID-19 confers considerably longer-lasting and stronger protection against the Delta variant of the virus than vaccines.

"The natural immune protection that develops after a SARS-CoV-2 infection

offers considerably more of a shield against the Delta variant of the pandemic coronavirus than two doses of the Pfizer-BioNTech vaccine, according to a large Israeli study that some scientists wish came with a 'Don't try this at home' label," *Science* reported Thursday. "The newly released data show people who once had a SARS-CoV-2 infection were much less likely than vaccinated people to get Delta, develop symptoms from it, or become hospitalized with serious COVID-19."

Put another way, vaccinated individuals were 27 times more likely to get a symptomatic COVID infection than those with natural immunity from COVID.



A Death Blow to Vaccine Passports?

The findings come as many governments around the world are demanding citizens acquire "vaccine passports" to travel. New York City, France, and the Canadian provinces of Quebec and British Columbia are among those

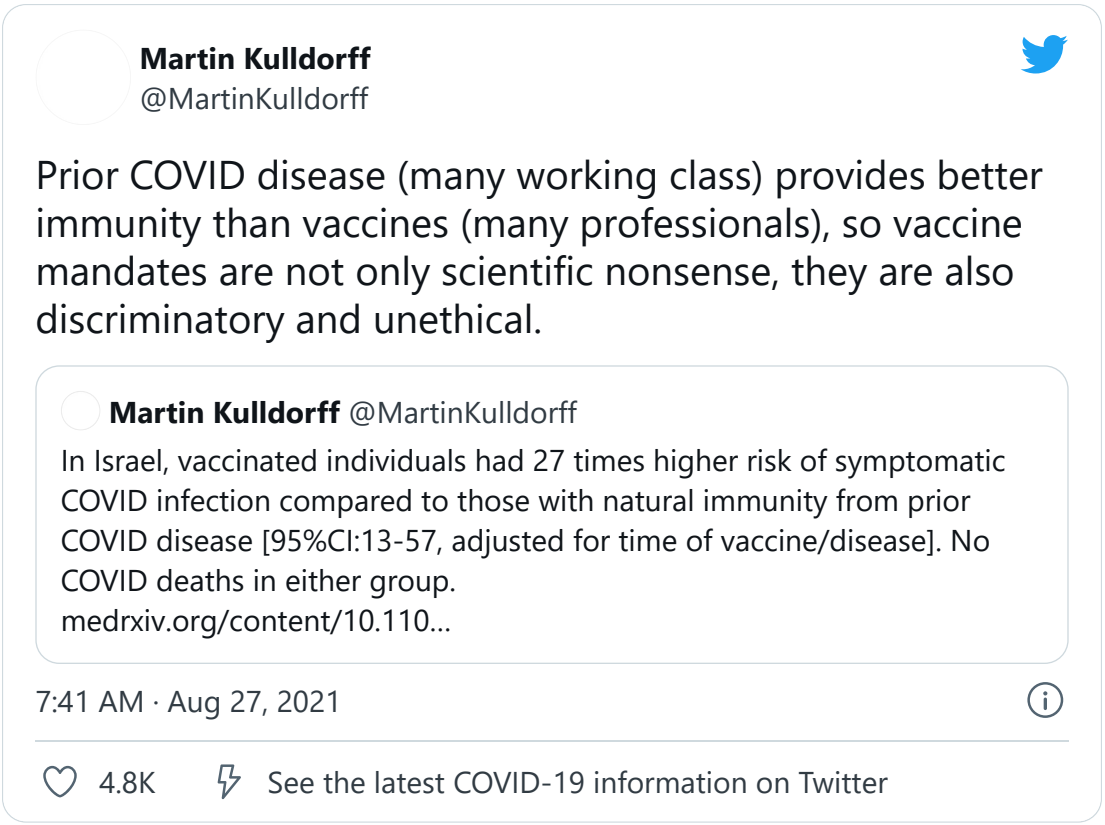
who have recently embraced vaccine passports.

Meanwhile, Australia has floated the idea of making higher vaccination rates a condition of lifting its lockdown in jurisdictions, while President Joe Biden is considering making interstate travel unlawful for people who have not been vaccinated for COVID-19.

Vaccine passports are morally dubious for many reasons, not the least of which is that freedom of movement is a basic human right. However, vaccine passports become even more senseless in light of the new findings out of Israel and revelations from the CDC, some say.

Harvard Medical School professor Martin Kulldorff said research showing that natural immunity offers exponentially more protection than vaccines means vaccine passports are both unscientific and discriminatory, since they disproportionately affect working class individuals.

"Prior COVID disease (many working class) provides better immunity than vaccines (many professionals), so vaccine mandates are not only scientific nonsense, they are also discriminatory and unethical," Kulldorff, a biostatistician and epidemiologist, observed on Twitter.

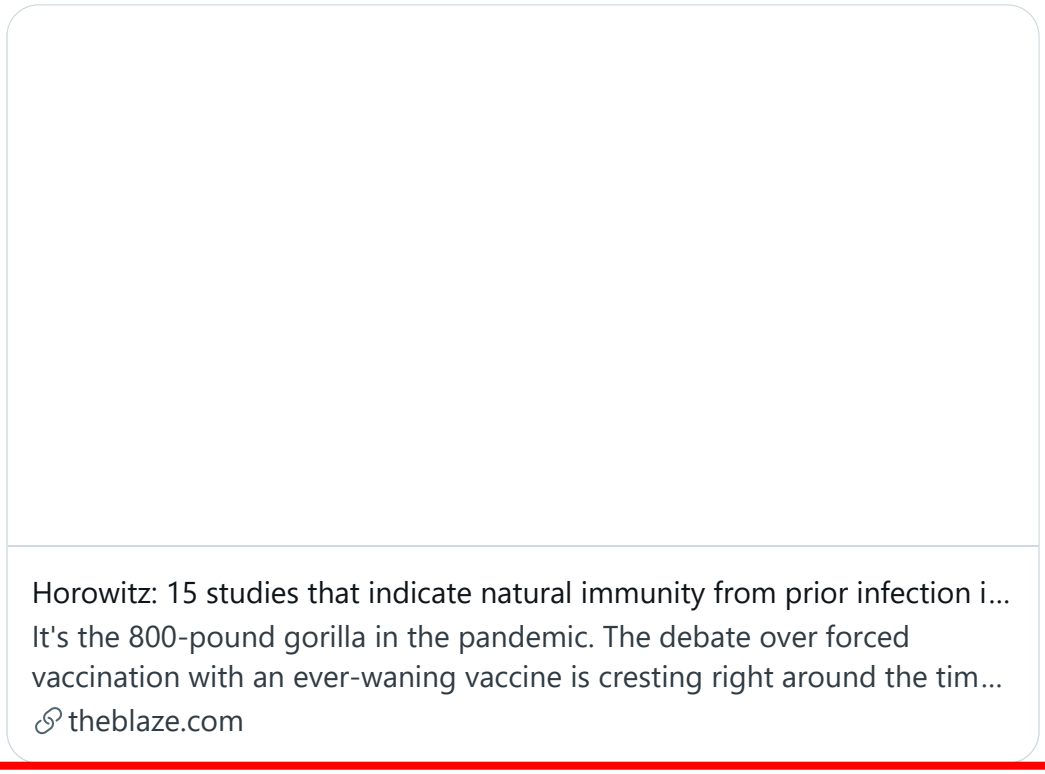


Nor is the study out of Israel a one-off. Media reports show that no fewer than 15 academic studies have found that natural immunity offers immense protection from COVID-19.

Thomas Massie
@RepThomasMassie

"Among the most fraudulent messages of the CDC's campaign of deceit is to force the vaccine on those with prior infection, who have a greater degree of protection against all versions of the virus than those with any of the vaccines."

15 studies show...



Horowitz: 15 studies that indicate natural immunity from prior infection i...
It's the 800-pound gorilla in the pandemic. The debate over forced vaccination with an ever-waning vaccine is cresting right around the tim...
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6:40 AM · Aug 26, 2021

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Moreover, CDC research shows that vaccinated individuals still get infected with COVID-19 and carry just as much of the virus in their throat and nasal passage as unvaccinated individuals

"High viral loads suggest an increased risk of transmission and raised concern that, unlike with other variants, vaccinated people infected with Delta can transmit the virus," CDC Rochelle Director Walensky noted following a Cape Cod outbreak that included mostly vaccinated individuals.

These data suggest that vaccinated individuals are still spreading the virus much like unvaccinated individuals.

The Bottom Line

Vaccine passports would be immoral and a massive government overreach even in the absence of these findings. There is simply no historical parallel for governments attempting to restrict the movements of healthy people over a respiratory virus in this manner.

Yet the justification for vaccine passports becomes not just wrong but absurd in light of these new revelations.

People who have had COVID already have significantly more protection from the virus than people who've been vaccinated. Meanwhile, people who've not had COVID and choose to not get vaccinated may or may not be making an unwise decision. But if they are, they are principally putting only themselves at risk.

Jon Miltimore

Jonathan Miltimore is the Managing Editor of FEE.org. His writing/reporting has been the subject of articles in TIME magazine, The Wall Street Journal, CNN, Forbes, Fox News, and the Star Tribune.
Bylines: Newsweek, The Washington Times, MSN.com, The Washington Examiner, The Daily Caller, The Federalist, the Epoch Times.

EXHIBIT E

ARUTZ SHEVA 7
israelnationalnews.com

Study: Recovered COVID patients don't benefit from vaccine

New US study finds natural infection to COVID provides robust long-term immunity, with vaccination providing no added benefit.

David Rosenberg, 8/1/2021 כ"ג באב תשפ"א,

iStock

EXHIBIT E

A new study on the effects of natural infection by the coronavirus suggests that there may be little to no benefit for recovered SARS-CoV-2 patients in receiving vaccines against the coronavirus.

According to the study, conducted in Cleveland, Ohio and published in the MedRxiv journal last month, people who were infected with the coronavirus enjoy significant long-term immunity from the virus, which is unlikely to be increased by being injected with one of the coronavirus vaccinations now on the market.

The study followed 52,238 employees of the Cleveland Clinic Health System, monitoring infections among vaccinated and unvaccinated workers, and the incidents of reinfection among both vaccinated and unvaccinated workers.

Of the 52,238 employees tracked in the study, 2,579 had previously tested positive for the coronavirus, while 49,659 had never been confirmed as carrying the virus.

Fifty-three percent of the 2,579 employees who had been infected with the virus previously remained unvaccinated (1,359 people), compared to 41% (22,777) of the employees who were never diagnosed with the virus.

Zero previously infected employees were reported to have become infected again with the virus, regardless of their vaccination status.

Vaccination significantly reduced the risk of coronavirus infection, the study found, but only among those who had not previously been infected.

The authors concluded that vaccination after natural infection is unlikely to have any benefit for recovered COVID patients.

“Individuals who have had SARS-CoV-2 infection are unlikely to benefit from COVID-19 vaccination, and vaccines can be safely prioritized to those who have not been infected before.”

Previous studies in Israel and Qatar have found extremely low levels of reinfection among recovered coronavirus patients.

More recent data collected by the Israeli Health Ministry in the midst of outbreaks of the Delta Variant found that there were far fewer cases of reinfection after natural infection than there were infections among vaccinated Israelis who had never been diagnosed with the virus previously.

With a total of 835,792 Israelis known to have recovered from the virus, the 72 instances of reinfection amount to 0.0086% of people who were already infected with COVID.

By contrast, Israelis who were vaccinated were 6.72 times more likely to get infected after the shot than after natural infection, with over 3,000 of the 5,193,499, or 0.0578%, of Israelis who were vaccinated getting infected in the latest wave.

Cell Reports
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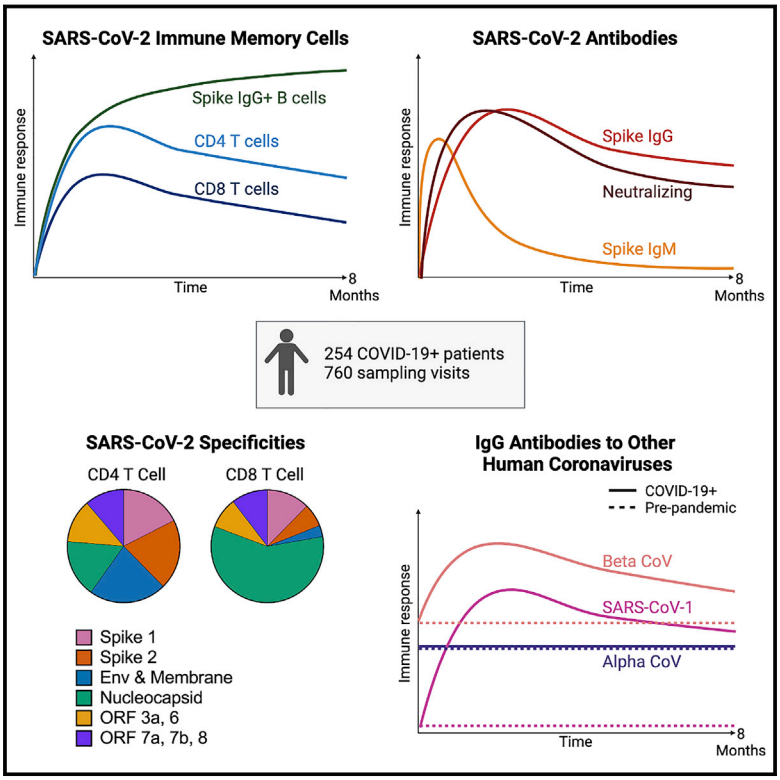
Article

Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells

Graphical abstract



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In brief

Cohen et al. evaluate immune responses longitudinally in 254 COVID-19 patients over 8 months. SARS-CoV-2-specific binding and neutralizing antibodies exhibit biphasic decay, suggesting long-lived plasma cell generation. Memory B cells remain stable; CD4 and CD8 memory T cells are polyfunctional. Thus, broad and effective immunity may persist long-term following COVID-19.

Highlights

- Most recovered COVID-19 patients mount broad, durable immunity after infection
- Neutralizing antibodies show a bi-phasic decay with half-lives >200 days
- Spike IgG+ memory B cells increase and persist post-infection
- Durable polyfunctional CD4 and CD8 T cells recognize distinct viral epitope regions

Cohen et al., 2021, Cell Reports Medicine 2, 100354
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CellPress
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Article

Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells

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SUMMARY

Ending the COVID-19 pandemic will require long-lived immunity to SARS-CoV-2. Here, we evaluate 254 COVID-19 patients longitudinally up to 8 months and find durable broad-based immune responses. SARS-CoV-2 spike binding and neutralizing antibodies exhibit a bi-phasic decay with an extended half-life of >200 days suggesting the generation of longer-lived plasma cells. SARS-CoV-2 infection also boosts antibody titers to SARS-CoV-1 and common betacoronaviruses. In addition, spike-specific IgG+ memory B cells persist, which bodes well for a rapid antibody response upon virus re-exposure or vaccination. Virus-specific CD4+ and CD8+ T cells are polyfunctional and maintained with an estimated half-life of 200 days. Interestingly, CD4+ T cell responses equally target several SARS-CoV-2 proteins, whereas the CD8+ T cell responses preferentially target the nucleoprotein, highlighting the potential importance of including the nucleoprotein in future vaccines. Taken together, these results suggest that broad and effective immunity may persist long-term in recovered COVID-19 patients.

INTRODUCTION

The COVID-19 pandemic caused by the rapid spread of SARS-CoV-2, a novel betacoronavirus, continues to cause significant morbidity and mortality. The induction of effective early immune control of SARS-CoV-2 and durable immune memory is critical to prevent severe disease and to protect upon re-exposure. SARS-CoV-2 infection induces polyclonal humoral and cellular responses targeting multiple viral proteins described in cross-sectional and longitudinal studies.[1] More comprehensive, quantitative analyses with extensive serial sampling in larger numbers of COVID-19 patients are limited and could resolve some conflicting views about the durability of humoral immunity. Importantly, defining the frequency, immune function, and specificity of the antibodies; memory B and T cell responses among COVID-19 patients; and identifying when they appear and how long they persist can provide understanding of the integral components for long-lived immunity to SARS-CoV-2 and potentially other human coronaviruses that emerge in the future.[2]

We initiated two prospective COVID-19 patient cohorts in Seattle and Atlanta during the first surge of the pandemic to investigate long-term immunity to SARS-CoV-2. Among 254 COVID-19 patients enrolled and frequently sampled, we identify binding and neutralizing antibodies to SARS-CoV-2 as well as antigen-specific B and T cells elicited early after infection, define their specificities, quantify the extent of antibody boosting of cross-reactive

responses to other coronaviruses, and further characterize the decay rate and durability of these immune parameters over 250 days. We employ highly standardized or validated assays that are also being used to evaluate immunity in recent and ongoing clinical vaccine trials.[3-5] This in-depth longitudinal study demonstrates that durable immune memory persists in most COVID-19 patients, including those with mild disease, and serves as a framework to define and predict long-lived immunity to SARS-CoV-2 after natural infection. This investigation will also serve as a benchmark for immune memory induced in humans by SARS-CoV-2 vaccines.

RESULTS

COVID-19 study population

COVID-19-confirmed patients were recruited into our longitudinal study of SARS-CoV-2 specific B and T cell memory after infection. A total of 254 patients were enrolled at two sites, Atlanta and Seattle, starting in April 2020 and returned for follow up visits over a period of 250 days. We were able to collect blood samples at 2–3 time points from 165 patients and at 4–7 time points from another 80 patients, which allowed us to perform a longitudinal analysis of SARS-CoV-2-specific B and T cell responses on a large number of infected patients. The demographics and baseline characteristics of this cohort are described in Table S1. The study group was 55% female and 45% male and between 18 and 82 years old (median, 48.5 years). Based on World Health Organization (WHO) guidelines of disease severity, 71% of study participants exhibited mild disease, 24% had moderate disease, and 5% experienced severe disease.

Antibody responses to SARS-CoV-2 spike protein show a bi-phasic decay with an extended half-life

Binding antibodies to the SARS-CoV-2 full-length spike protein, to the receptor binding domain (RBD), and to the N-terminal domain (NTD) of the spike protein were assessed in COVID-19 patients (n = 222) over a period of 8 months post symptom onset. We included healthy individuals age 18–42 years as negative controls whose longitudinal blood samples were collected before the emergence of the COVID-19 pandemic. These pre-pandemic samples (n = 51) were from recipients of either the seasonal inactivated influenza vaccine (n = 27, collected from 2014-2018) or the live yellow fever virus (YFV-17D) vaccine (n = 24, collected from 2005–2007). The Mesoscale multiplex assay was used to measure IgG, IgA, and IgM antibody responses to SARS-CoV-2 proteins in the COVID-19 patients and in the pre-pandemic healthy controls.

The magnitude of serum IgG antibodies binding to the SARS-CoV-2 spike protein increased in 92% of COVID-19 convalescent participants (n = 222) relative to pre-pandemic controls (Figure 1A). The IgG responses to SARS-CoV-2 spike, RBD, and NTD declined over time with half-lives of 126 (95% confidence interval [95% CI] [107, 154]), 116 (95% CI [97, 144]), and 130 (95% CI [110, 158]) days, respectively, as estimated by an exponential decay model (Figures 1A–1C and S1A). We also estimated antibody waning using a power law model, which models a scenario in which the rate of antibody decay slows over time. The power law model produced a better fit for the decay of the SARS-CoV-2 spike, RBD, and NTD binding IgG antibodies (DAICs > 10), suggesting that spike-specific antibodies plateau over time. Because the decay rate changes over time, the half-life is predicted to change over time as well; therefore, we used the power law model to estimate the half-lives at 120 days after symptom onset. The power law estimated half-lives for the IgG antibody responses to spike ($t_{1/2}$ = 238 days), RBD ($t_{1/2}$ = 209 days), and NTD ($t_{1/2}$ = 244 days) were longer than those estimated by the exponential decay model (Figures S1A and S1C), indicating that the concentration of these IgG antibodies may be starting to stabilize. IgA (Figures 1D–1F) and IgM (Figures 1G–1I) antibodies reactive to the SARS-CoV-2 spike also increased after SARS-CoV-2 infection but were detected at lower levels and declined faster than the SARS-CoV-2-reactive IgG antibodies. As expected, spike-binding IgM decayed more rapidly than spike-binding IgA and IgG. Taken together, these results show that antibody responses, especially IgG antibody, were not only durable in the vast majority of patients in the 250 day period, but also that the bi-phasic decay curve suggests the generation of longer lived plasma cells producing antibody to the SARS-CoV-2 spike protein.

We also examined the antibody response to the SARS-CoV-2 nucleocapsid protein in these infected patients. As expected, the COVID-19 patients showed higher levels of antibody to the nucleocapsid protein compared to the pre-pandemic healthy controls (Figure S2). However, the nucleocapsid-specific antibodies declined with a much shorter half-life of 63 days (95% CI [58, 70]) compared to the spike protein antibodies (Figures S1A–S1C). Also, the nucleocapsid reactive IgG decay rate was best fit by the exponential model and not the power law model in contrast to what we observed with the spike IgG antibody decay rate (Figure S1A). Thus, the nucleocapsid reactive IgG not only declined much faster but also showed less evidence of stabilizing antibody levels, consistent with a response driven disproportionately by short-lived antibody secreting cells – at least at this stage of the immune response.

Stable and long-lived antibody responses to common human alpha- and betacoronaviruses in pre-pandemic healthy controls

We were interested in determining if SARS-CoV-2 infection had any effect on the levels of antibody to the circulating human alpha- and betacoronaviruses. As a prelude to this question, we first examined antibody levels to the spike protein of the two circulating alphacoronaviruses (229E and NL63) and the two betacoronaviruses (HKU1 and OC43) in our pre-pandemic samples. As shown in Figure 2, all 51 pre-pandemic samples had clearly detectable levels of IgG and IgA antibodies to the spike proteins of the four human coronaviruses. This is the expected result since seropositivity to these coronaviruses is very high in the adult population, but what was quite interesting was the remarkable stability of these antibody responses over a 200-day period in the pre-pandemic serum samples (shown as red lines in Figure 2). These were essentially flat lines with no decline in the antibody levels and question the prevailing belief that antibody responses to the endemic coronaviruses are short-lived.[6-8] While some occasional boosting of these childhood-acquired coronavirus infections cannot be ruled out, these data showing such stable antibody titers are best explained by

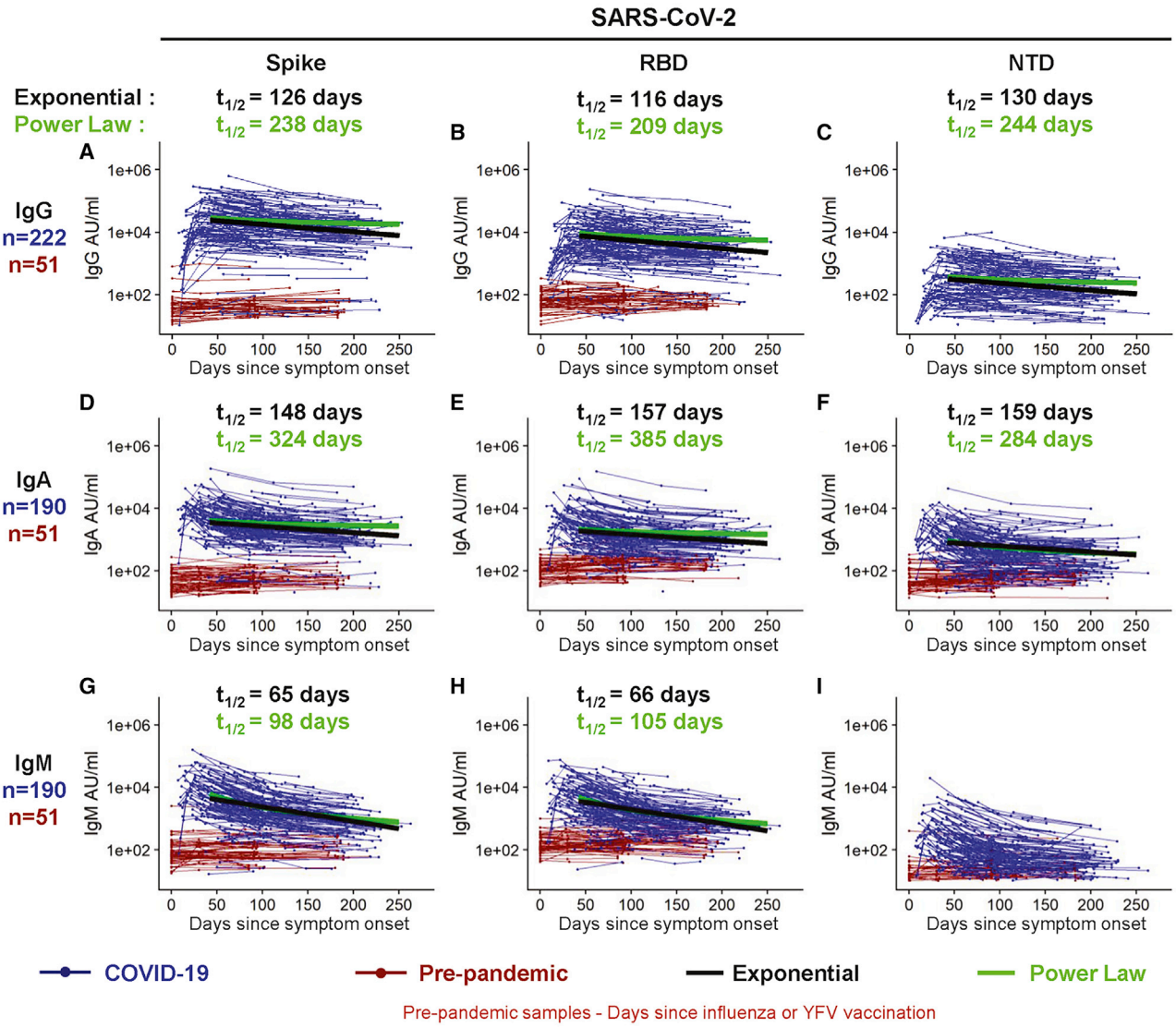

Figure 1. Longitudinal SARS-CoV-2 spike-binding antibody responses

IgG (A–C), IgA (D–F), and IgM (G–I) antibodies reactive to SARS-CoV-2 spike (A, D, G); spike receptor binding domain (RBD, [B, E, and H]), and the spike N-terminal domain (NTD, [C, F, and I]) were measured in triplicate by an electrochemiluminescent multiplex immunoassay and reported as arbitrary units per ml (AU/mL) as normalized by a standard curve. Longitudinal antibody titers of COVID-19 patients (in blue, n = 222 COVID-19+ for IgG; n = 190 COVID-19+ for IgA and for IgM) are plotted over days since symptom onset, whereas longitudinal pre-pandemic donor samples (in red, n = 51 for IgG, IgA, and IgM) were collected in the course of a non-SARS-CoV-2 vaccine study before 2019 and plotted over days since immunization. IgG decay curves and half-lives estimated by an exponential decay model are shown in black, and the decay curves and half-lives at day 120 post symptom onset estimated by a power law model are shown in green.

the persistence of long-lived plasma cells in the bone marrow many years after infection.[9-13]

COVID-19 infection results in increased levels of antibodies to two common human betacoronaviruses (HKU1 and OC43) and to SARS-CoV-1

We next examined if SARS-CoV-2 infection had any impact on the levels of antibodies to the other human coronaviruses. We measured IgG, IgA, and IgM antibody binding to the spike proteins of other known human coronaviruses in the COVID-19 patients (n = 222 for IgG and n = 190 for IgA and IgM) and compared these data to the 51 pre-pandemic healthy donor samples. In the COVID-19 patients, IgG and IgA antibodies to the alphacoronaviruses 229E and NL63 did not show any significant changes compared to the antibody levels in the pre-pandemic healthy controls (Figures 2A, 2B, 2F, and 2G; Figures S1C and S1D). In contrast, the IgG and IgA antibodies to betacoronaviruses HKU1 and OC43 were substantially elevated in COVID-19 patients relative to pre-pandemic controls (Figures 2C, 2D, 2H, and 2I; Figures S1C and S1D; $p < 0.0001$). After this boost, HKU1 and OC43 IgG antibody levels declined with estimated half-lives of 288 (95% CI [235, 372]) and 212 (95% CI [176, 268]) days, respectively (exponential decay

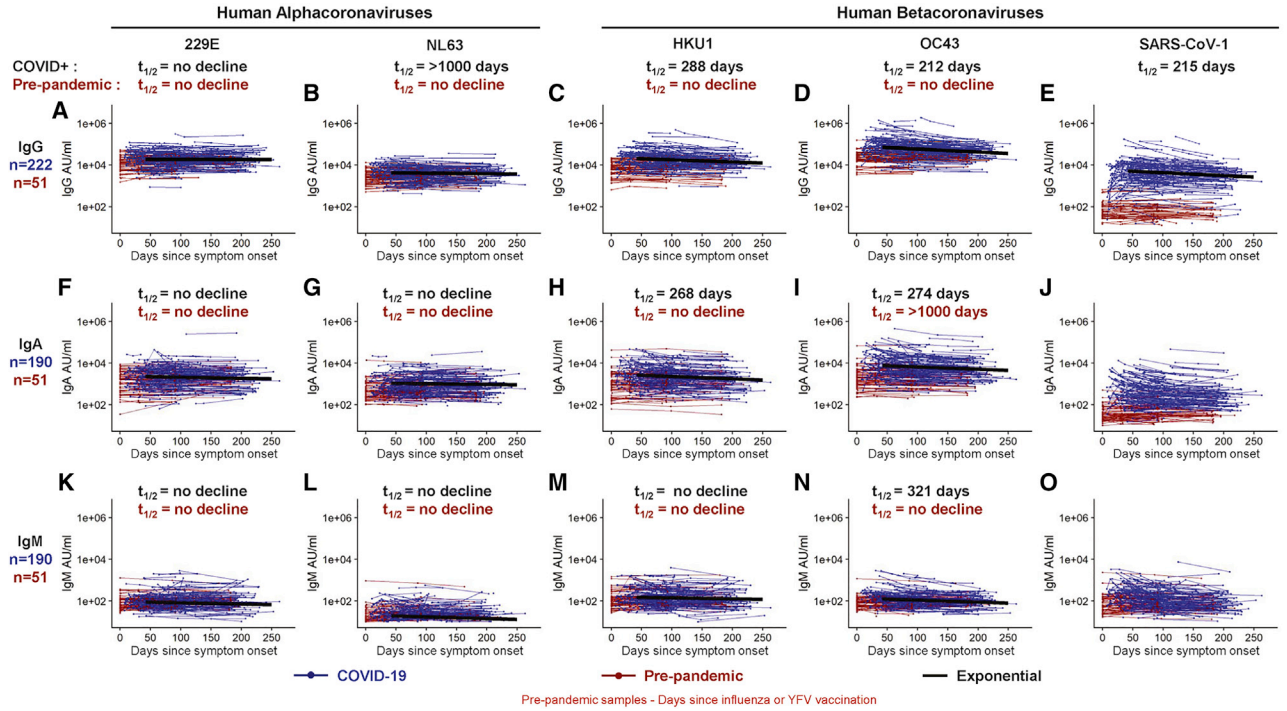

Figure 2. Longitudinal binding antibody responses to other coronavirus spike proteins

IgG (A–E), IgA (F–J), and IgM (K–O) antibody responses in sera collected from COVID-19+ patients (in blue, n = 222 for IgG; n = 190 for IgA and IgM) and pre-pandemic donors (in red, n = 51 for IgG, IgA and IgM) that were measured to 229E spike (A, F, and K), NL63 spike (B, G, and L), HKU1 spike (C, H, and M), OC43 spike (D, I, and N), and the SARS-CoV-1 spike protein (E, J, and O) in triplicate. Longitudinal antibody titers of COVID-19 patients are plotted over days since symptom onset, whereas longitudinal pre-pandemic donor samples were collected in the course of a non-SARS-CoV-2 vaccine study before 2019 and plotted over days since immunization. Antibody responses were measured by an electrochemiluminescent multiplex immunoassay and reported as arbitrary units per ml (AU/mL) as normalized by a standard curve. IgG decay curves and half-lives estimated by an exponential decay model are shown in black. There was no significant decline in IgG reactive to endemic alpha and betacoronaviruses in longitudinal samples collected in healthy donors before the pandemic (red, [A–D]).

model). IgM levels to common betacoronaviruses HKU1 and OC43 were low in both pre-pandemic controls and COVID-19 patients (Figures 2M and 2N). While pre-existing exposure and antibodies against HKU1 and OC43 betacoronaviruses are common in adults, pre-existing SARS-CoV-1 exposure is rare and antibody levels to SARS-CoV-1 spike protein were very low (essentially negative) in the pre-pandemic healthy controls. However, SARS-CoV-1 spike-reactive antibodies increased significantly after SARS-CoV-2 infection. These increases were quite striking for IgG ($p = 0.0038$) and also IgA ($p = 0.0084$) and most likely represent cross-reactive antibodies directed to SARS-CoV-2 spike epitopes that are conserved between SARS-CoV-2 and SARS CoV-1[14]. These newly induced cross-reactive IgG antibodies generated after COVID-19 infection declined with an estimated half-life of 215 days (95% CI [168, 298]) (exponential decay model) (Figure 2). Taken together, these results show that people infected with SARS-CoV-2 may have also have some heightened immunity against the common human betacoronaviruses and more importantly against SARS-CoV-1.

Durable neutralizing antibody responses to SARS-CoV-2 in infected patients

Neutralizing antibodies were measured with a live virus focus reduction neutralization test that uses a recombinant SARS-CoV-2 virus expressing the fluorescent reporter gene mNeonGreen (FRNT-mNG) (Figure 3A). During the first 250 days post-symptom onset, $FRNT_{50}$ titers varied considerably between individuals and ranged from < 20 to 3726 (Figure 3A). Of the 183 individuals for whom longitudinal neutralization titers were assayed, 140 (77%) had at least one time point with neutralization titers above the limit of detection (> 20). Seventy-five percent (43/57) of COVID-19 patients generated serum neutralizing antibodies between 30–50 days after symptom onset and similarly 72% (48/67) had measurable titers between 180–263 days after symptom onset. Using an exponential decay model, we evaluated the kinetics of neutralizing antibody titers after day 42 and estimated a half-life of 150 days (95% CI [124, 226]). However, similar to the spike-reactive IgG binding antibodies, we hypothesized that the neutralizing antibody rate of decay may actually slow over time during the recovery period. To address this, we fit a power law to the data. The power law model fit significantly better than the exponential decay model (DAIC = 9) and estimated the half-life of neutralizing antibody responses at 120 days post-symptom onset to be 254 days (95% CI [183, 400]).

Next, we assessed the relationship between the levels of spike and RBD binding antibodies and SARS-CoV-2 neutralization. Figures 3B and C show the SARS-CoV-2 spike and RBD binding antibody response kinetics of the 183 participants for whom

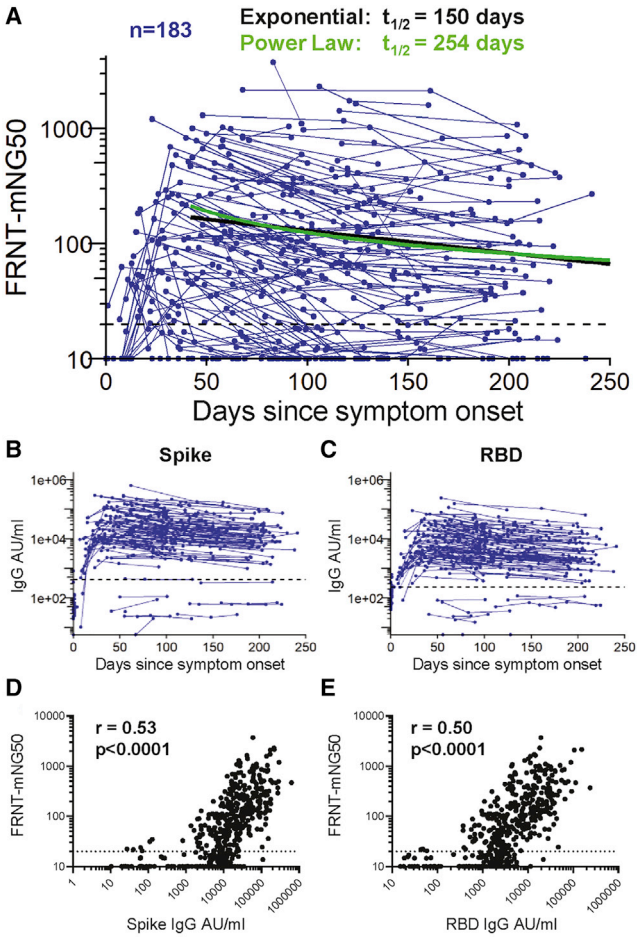

Figure 3. Neutralizing antibody responses to SARS-CoV-2

(A) *In vitro* serum neutralization antibody titers to SAR-CoV-2 were measured in duplicate by focus-reduction neutralization assay COVID-19 patients (n = 183). The limit of detection is indicated with a dashed line at FRNT-mNG$_{50}$ = 20. The half-life estimated by the exponential decay model (black) is 150 days, whereas the half-life estimated at day 120 using the power law model (green) is 254 days. (B and C) IgG antibody titers reactive to SARS-CoV-2 spike (B) and RBD (C) of the matched 183 COVID-19 for whom neutralization titers were assessed. The geometric mean titer plus 3 standard deviations of pre-pandemic samples is indicated by a dashed line.

(D and E) SARS-CoV-2 spike (D) and RBD (E) reactive IgG levels correlated with neutralization titers at the matched time point (repeated-measures correlation, $p < 0.0001$). The limit of detection is indicated with a dashed line at FRNT-mNG$_{50}$ = 20.

neutralization titers were assessed. These exhibited a wide range of antibody binding levels ranging from non-responders (n = 11) who did not elicit antibody titers above those of pre-pandemic controls (defined as a COVID-19 patient titer below the mean pre-pandemic antibody titer plus three standard deviations, see dashed line on Figures 3B and 3C) to those with IgG levels > 200,000 AU/mL. Spike and RBD binding IgG levels correlated significantly with the neutralization titers (Figure 3D, E; $p < 0.0001$).

Taken together, our findings show that induction of neutralizing antibodies occurs in the majority of COVID-19 patients. These neutralizing antibodies can persist over the 8–9 month period following infection, and show a correlation with spike and RBD binding IgG.

SARS-CoV-2 spike and RBD-specific memory B cells increase for several months after infection and then plateau over 8 months

Memory B cells (MBC) are an important component of humoral immunity and contribute to viral control by generating antibody responses upon re-exposure to the pathogen. We used full-length spike and RBD antigen probes to quantify the frequencies of SARS-CoV-2 spike- and RBD-specific MBC in longitudinal PBMC samples from 111 COVID-19 patients (Figure 4) and from 29 pre-pandemic controls (Figures S3A and S3B). Our flow cytometric gating strategy to identify SARS-CoV-2-specific MBC and classify them as IgG, IgM, and IgA MBC isotypes is shown in Figure 4A.

Among the total MBC, the spike IgG+ MBCs were significantly increased in COVID-19 patients (n = 111; Figure 4B) in comparison to pre-pandemic controls (n = 29; Figure S3A) (median increase, 0.73% versus 0.02%; $p < 0.0001$). After a steep early expansion over the first 2-3 months, the spike IgG+ MBC persisted in COVID-19 patients with no decline out to 250 days post symptom onset. These findings (Figure 4B) are supported by a positive slope (0.004) from the model of the longitudinal spike IgG+ MBC responses after day 30 (95% CI [0.002, 0.006], $p < 0.001$; Figures S4A and S4B).

The spike IgM+ MBC appeared within the first 2 weeks post-symptom onset and quickly declined (Figures 4C and 4D). The decay continued after day 30 (slope = −0.007, 95% CI [-0.010, −0.005], $p < 0.001$). One month after symptom onset, 56% of spike MBC were IgG+, which increased to a peak of 80% at 5–6 months (Figure 4D). Circulating spike IgA+ MBC were also detectable in many subjects at low frequencies and without significant change over time (day 30–250: slope = 0.000, 95% CI [-0.002, 0.002], $p = 0.91$, Figure 4D).

Since the RBD contains the primary neutralizing epitopes on the spike, we also used an RBD-specific probe to characterize this subset of spike-specific memory B cells. Overall, approximately 20% of the spike IgG+ memory B cells targeted the RBD, which was consistent across subjects and time (Figures 4E and 4F). As expected, RBD+ IgM+ MBC emerged early in infection and subsequently switched to RBD+ IgG+ MBCs, which gradually increased during follow-up (day 30–250: slope = 0.004, 95% CI [0.002, 0.005], $p < 0.001$, Figure 4E). Thus, the maintenance of circulating spike- and RBD-specific IgG memory B cells suggests that these cells could be recruited for a rapid secondary response following re-exposure or vaccination.

Induction of durable and polyfunctional virus specific memory CD4+ and CD8+ T cells in infected patients

CD4+ T cells are critical for generation of high affinity antibody responses and can also have anti-viral effects. In addition, they provide help for CD8+ T cell responses, which are vital for killing infected cells and mediating viral clearance. Thus, we next examined virus-specific CD4+ and CD8+ T cell responses longitudinally in COVID-19 patients and uninfected controls using a high-dimensional, multi-parameter *ex vivo* intracellular cytokine staining (ICS)

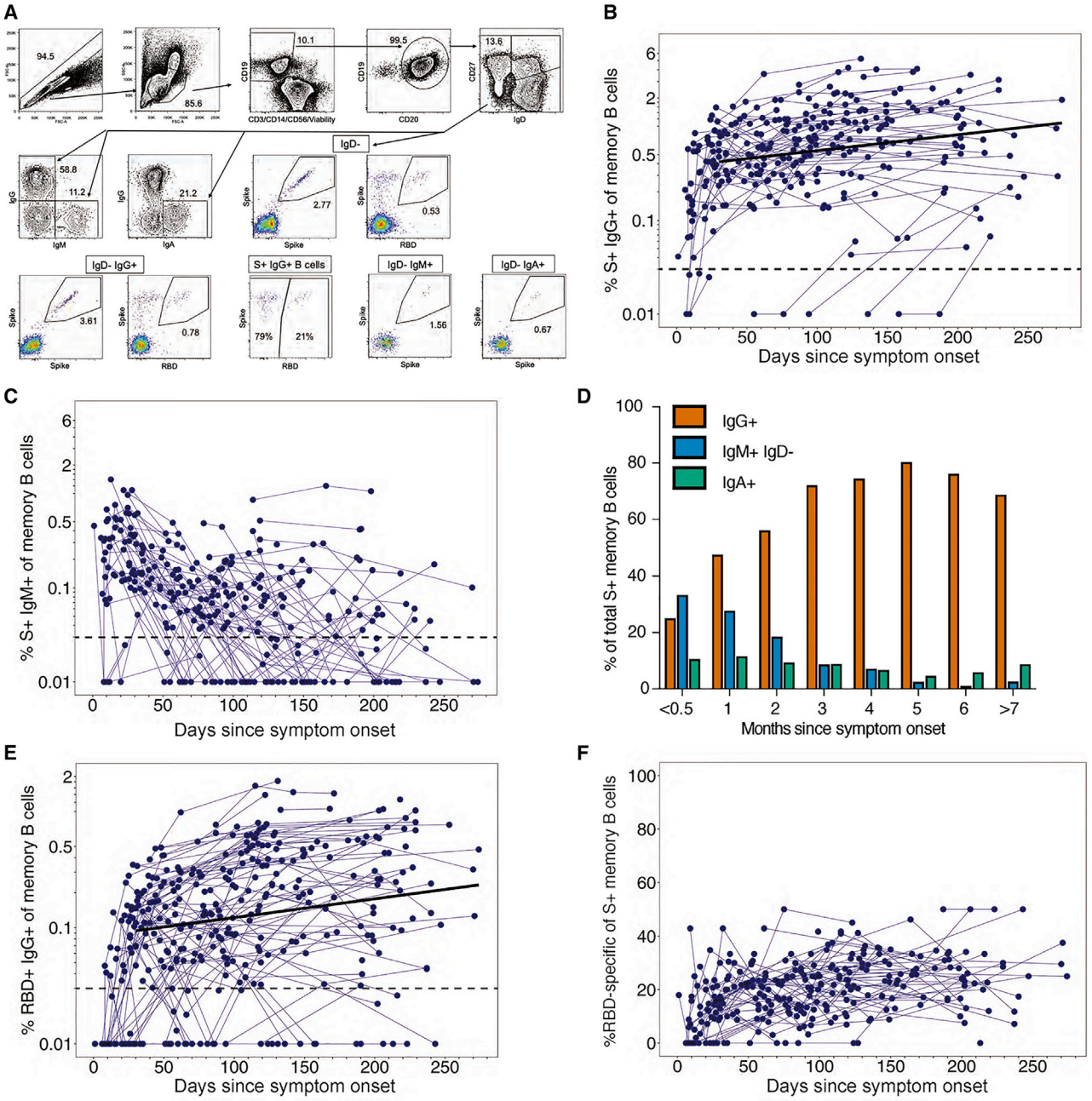

Figure 4. SARS-CoV-2 spike and RBD-specific memory B cells

(A) Representative memory B cell gating strategy is shown for identification of SARS-CoV-2 spike and RBD-specific IgD- IgG+, IgD- IgM+, and IgD- IgA+ memory B cells in PBMCs from a SARS-CoV-2 convalescent participant.

(B and C) The frequency of spike+ (B) IgG+ and (C) IgM+ memory B cells out of memory B cells (IgD- CD19+ CD20+) is displayed over time from initial symptom onset among SARS-CoV-2-infected subjects (n = 105 subjects; measured in singlet replicates). The dashed line indicates the limit of detection. The bold line represents the median fitted curve from a linear mixed effects model of post-day 30 responses.

(D) The median percent of spike+ memory B cells expressing IgG, IgM or IgA isotypes was assessed at monthly intervals post-symptom onset.

(E) The frequency of RBD+ IgG+ of memory B cells over time (n = 141).

(F) The proportion of S+ IgG+ memory B cells that are specific for the receptor binding domain are depicted over time.

assay. The assay is sensitive, precise, and specific for detection of antigen-specific T cells expressing multiple cytokines and effector molecules following a short-term (6 h) stimulation with peptide pools. Our lab developed and validated the assay, and we are currently using the method to quantitate Th1/Th2 CD4+ and CD8+ T cell responses in SARS-CoV-2 vaccine trials. Here,

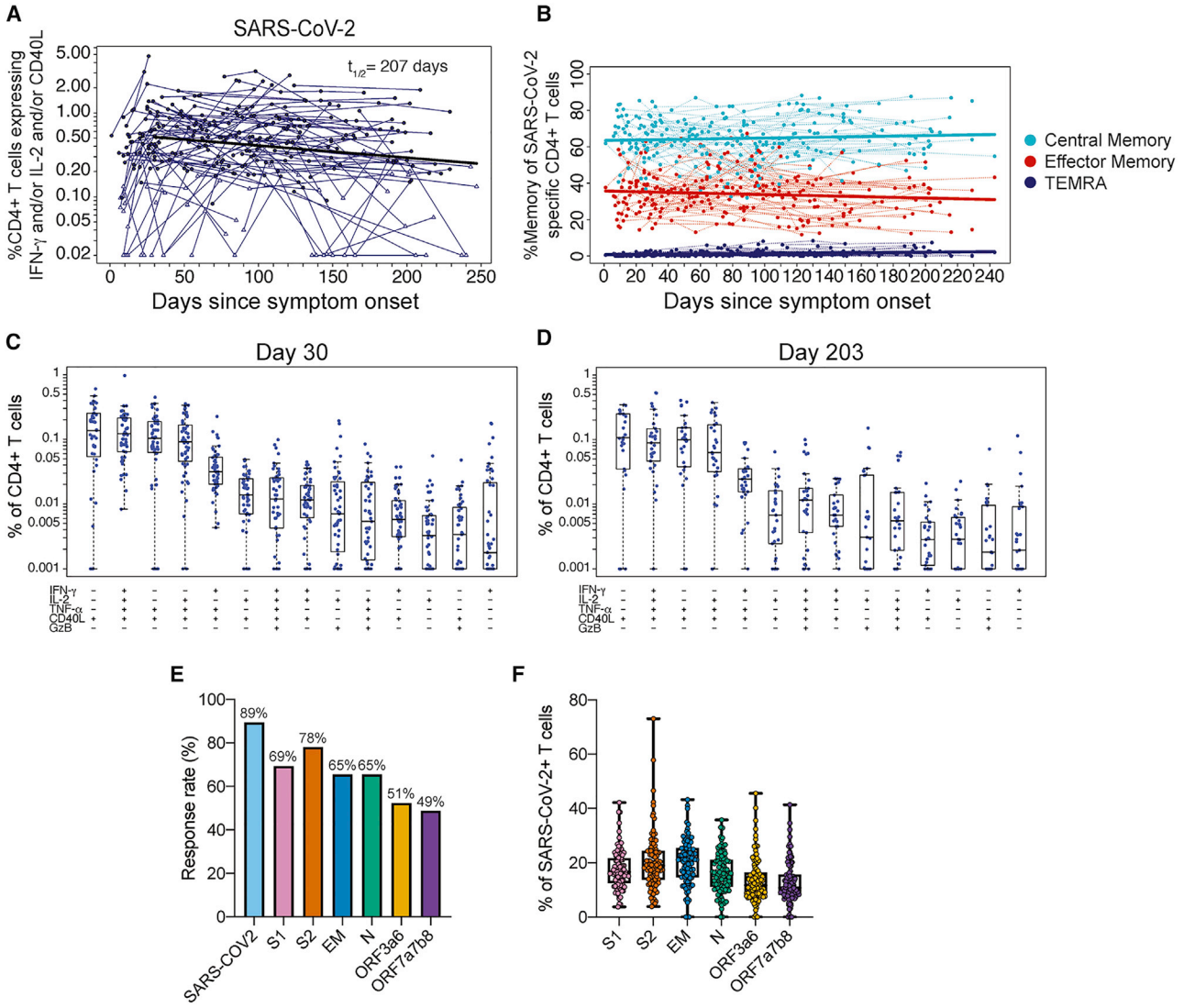

Figure 5. CD4+ T cell responses to SARS-CoV-2 antigens

(A) The sum of background-subtracted CD4+ T cells expressing *ex vivo* IFN-g, IL-2 and/or CD40L to peptide pools spanning SARS-CoV-2 structural proteins: S1, S2, envelope (E), membrane (M), nucleocapsid (N), and the following ORFs: 3a, 3b, 6, 7a, 7b, and 8 (n = 114; tested in singlets) for each individual/time point. Each sample that is "positive" (by MIMOSA) for at least one SARS-CoV-2 antigen is indicated by a solid circle, whereas samples that are "negative" for all of the SARS-CoV-2 antigens at that time point are indicated by open triangles. The bold line represents the median fitted curve from a nonlinear mixed effects model of post-day 30 responses among those with a positive response at $\geq$1 time point; $t_{1/2}$ is the median half-life estimated from the median slope, with 95% CI [104, 411].

(B) The proportion of SARS-CoV-2-specific CD4+ T cells expressing a specific memory phenotype over time: central memory (CCR7+ CD45RA-), effector memory (CCR7- CD45RA-), or T_{EMRA} (CCR7- CD45RA+); restricted to positive responders.

(C and D) Polyfunctionality of SARS-CoV-2-specific CD4+ T cells are shown at (C) 21-60 days since symptom onset (median, 30 days) and (D) > 180 days median post symptom onset (median, 203 days). Percentages of cytokine-expressing CD4+ T cells are background subtracted and only subsets with detectable T cells are displayed. Data shown were restricted to positive responders and a single data point per individual per time frame. All subsets were also evaluated for expression of IL-4, IL-5, IL-13, IL-17, and perforin and were found to be negative.

(E) Bar graphs indicate the proportion of COVID-19 convalescent patients who had a positive CD4+ T cell response to the individual SARS-CoV-2. peptide pool *ex vivo* stimulations. Some antigens were combined for stimulation as indicated.

(F) For each subject with positive SARS-CoV-2-specific CD4+ T cells, the proportion of the total SARS-CoV-2 responding CD4+ T cells that are specific for each stimulation.

we assessed T cell responses to the SARS-CoV-2 structural (S, E, M, and N) and accessory proteins (ORF 3a, 6, 7a, 7b, and 8) using overlapping peptide pools that span the sequences of these proteins.

Among COVID-19 patients, 89% (102/113) mounted CD4+ T cell responses (Figure 5A) recognizing at least one SARS-CoV-2 structural protein that was detectable at one or more visits. By contrast, SARS-CoV-2 specific CD4+ T cells were

rarely detected in the uninfected control group using this assay (Figure S3C). Antigen-specific CD4+ T cells expanded over the first month after infection and then gradually declined over subsequent months. Their estimated half-life was 207 days (95% CI [104, 211]) as shown in Figure 5A, and these findings are supported by the individual CD4+ T cell response levels and slopes after day 30 (slope = −0.0033, 95% CI [-0.0017, −0.0066], $p < 0.0001$) (Figures S4C and S4D). Of note, we observed a wide range in the total magnitude of responses, some reaching >1% of circulating CD4+ T cells, and an overall median frequency of 0.51% (Figures 5A and S5).

To better characterize the development of T cell memory in SARS-CoV-2 infection, we examined the differentiation profiles of virus-specific T cells longitudinally in COVID-19 patients. Based on CD45RA and CCR7 expression, SARS-CoV-2-specific CD4+ T cells were primarily central memory phenotype (CD 45RA- CCR7+) and to a lesser extent effector memory (CCRA-CCR7-); this profile of the memory T cell subsets was very consistent between subjects and stable over time (Figure 5B). The antigen-specific CD4+ T cells were Th1-biased with a predominant CXCR3+CCR6- phenotype, and highly polyfunctional, with simultaneous detection of antigen-specific CD154, IFN-γ, IL-2, TNF-α and less frequently granzyme B in the early expansion phase (21–60 days post symptom onset; median, 30 days) (Figure 5C). Interestingly, many of the virus-specific CD4+ T cells also exhibited this polyfunctionality at the memory time point (>180 days post symptom onset; median, 203 days) (Figure 5D). Circulating SARS-CoV-2-specific Th2 (IL-4, IL-5, and IL-13), Th17 (IL-17), or perforin-expressing subsets were not detected (Figures 5C and 5D).

Next, we examined the CD8+ T cell responses in COVID-19 patients and found that 69% generated CD8+ T cells recognizing at least one SARS-CoV-2 structural protein that were detectable at one or more visits (Figure 6A), in contrast to infrequent to rare, low-level antigen-specific responses in the uninfected control donors (Figure S3D). Expansion of CD8+ T cells occurred over the first month and then frequencies gradually declined, with a half-life of 196 days (95% CI [92, 417]) and a negative estimated slope after 30 days of symptom onset (slope = −0.004, 95% CI [-0.002, −0.008], $p < 0.0001$) (Figure 6A). The median frequency of SARS-CoV-2-specific CD8+ T cells was 0.2%, indicating a lower overall response magnitude than observed for CD4+ T cells. However, like the CD4+ T cells, a wide range in magnitudes was observed with many SARS-CoV-2-specific CD8+ T cell frequencies above 1% and even up to 12% (Figure 6A).

A very different pattern of phenotypic changes were observed with virus-specific CD8+ T cells compared to what we saw with the CD4+ T cells (Figure 6B versus Figure 5B). In contrast to the dominance of the central memory subset with SARS-CoV-2-specific CD4+ T cells, the vast majority of the virus-specific CD8+ T cells showed an effector memory phenotype during the early phase of the response. However, this population of SARS-CoV-2-specific effector memory (CD45RA-CCR7-) contracted over time (slope = −0.904, $p < 0.0001$; Figure 6B) and simultaneously there was an increase in the proportion of the TEMRA (CD45RA+CCR7-) subset of virus-specific CD8+ T cells (slope = 0.075, $p < 0.0001$; Figure 6B). A small but stable fraction of SARS-CoV-2-specific CD8+ T cells expressed a central memory phenotype (slope = 0.024, p = ns; Figure 6B).

The SARS-CoV-2-specific CD8+ T cells were highly polyfunctional with the highest magnitude populations secreting IFN-γ, TNF-α, and granzyme B; other dominant subsets also expressed IL-2 or perforin (Figures 6C and 6D). This polyfunctional profile was seen in the expansion phase (median 30 days; Figure 6C) and also at the later time points (>180 days post symptom onset; median 203 days; Figure 6D). It is important to note that this pattern of CD8+ T cell differentiation has been described in detail after vaccination in humans with the live attenuated yellow fever virus vaccine (YFV-17D).[15] This YFV-17D vaccine generates long-lived and functional virus-specific memory CD8+ T cells that persist in humans for decades.[15,16] That the CD8+ T cell differentiation program after COVID-19 infection resembles what is seen after YFV infection of human suggests that COVID-19 patients may also generate long-lived CD8+ T cell memory.

CD4+ and CD8+ cells target different SARS-CoV-2 antigen specificities

The majority of COVID-19 patients generated CD4+ T cells that recognized most SARS-CoV-2 viral structural and accessory proteins, with the highest percentage responding to S2 (78%) and S1 (69%) (Figures 5E and 5F). Among the COVID-19 subjects with positive responses, the proportion of SARS-CoV-2-specific CD4+ T cells reacting to each peptide pool was evenly distributed (Figure 5F). Thus, CD4+ T cells equally targeted multiple SARS-CoV-2 proteins.

In contrast to the results seen with CD4+ T cells, SARS-CoV-2-specific CD8+ T cells showed preferential recognition of the nucleocapsid protein. The dominant CD8+ T cell response rate was directed to the nucleocapsid (57%); followed by ORFs 7a, 7b, and/or 8 (25%); S1 (25%); ORFs 3a and/or 6 (16%); S2 (12%); and E and/or M (9%) (Figure 6E). Also, among the COVID-19 patients with CD8+ T cell responses, there was a bias with the largest percentage (median, 43%) reacting to the nucleoprocapsid protein (Figure 6F). While SARS-CoV-2 CD8+ T cell responses rates were much lower in uninfected controls, when present in a few control donors with lower frequencies, these were also targeted to the nucleocapsid protein (Figure S3D). A likely explanation for these findings is that in SARS-CoV-2 infection, antigen-presenting cells *in vivo* may display a higher proportion of peptides derived from the nucleocapsid protein and hence more nucleocapsid-specific CD8+ T cells are generated during infection. This has interesting implications suggesting that nucleocapsid-specific CD8+ T cells might be more efficient in recognizing virally infected cells.

Age and disease severity are significantly associated with magnitude of SARS-CoV-2 immune responses

We evaluated whether COVID-19 patient age, disease severity, or gender could account in part for the heterogeneity observed among the SARS-CoV-2-specific immune responses as estimated from the individual models (post day 30 for cellular and post day 42 for antibody responses). We observed that age was significantly associated with higher immune responses to SARS-CoV-2, independently of any covariation with disease

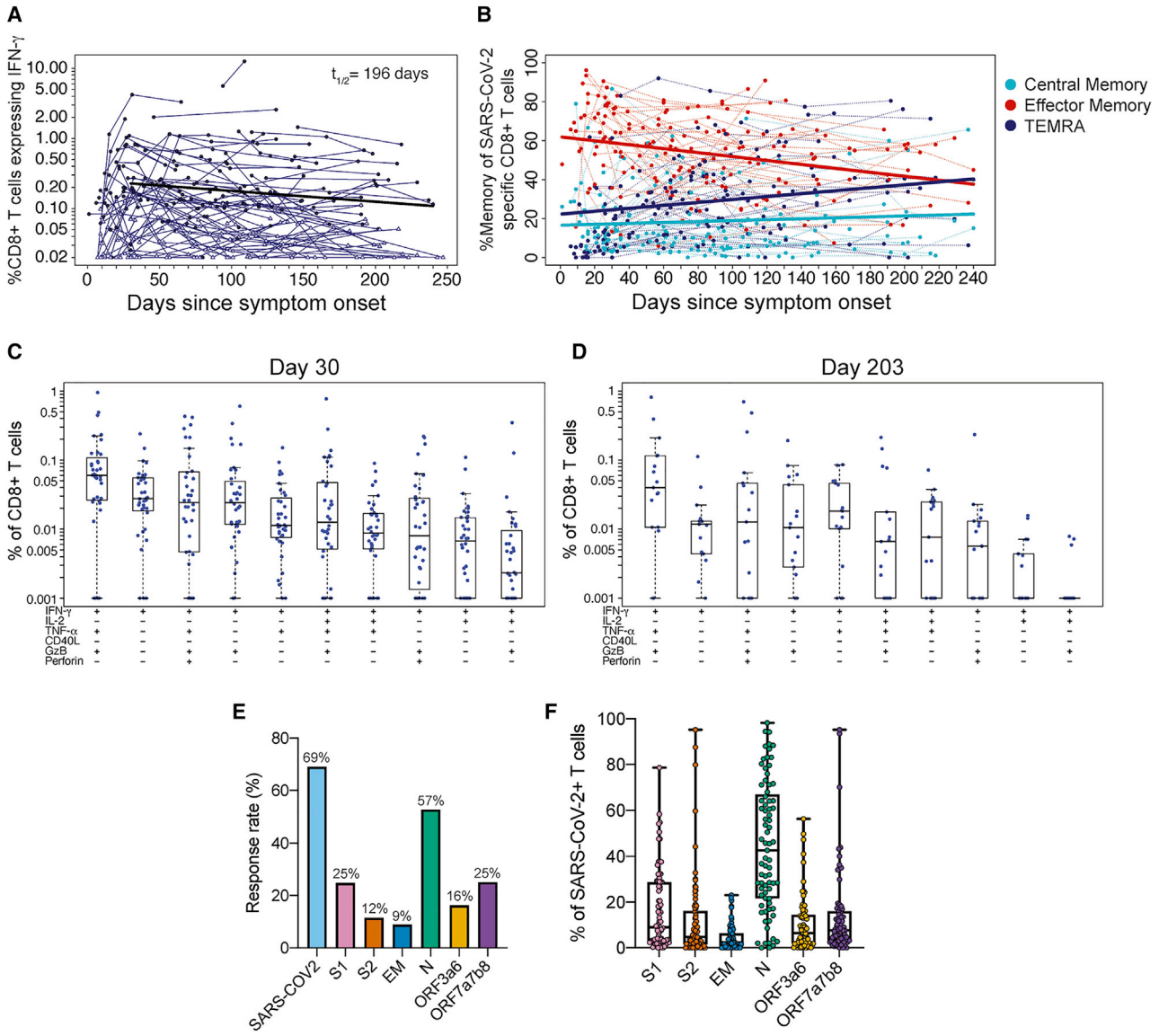

Figure 6. CD8+ T cell responses to SARS-COV-2 antigens

(A) The sum of background-subtracted CD8+ T cells expressing IFN-γ (with or without other cytokines), in response to peptide pools covering SARS-CoV-2 structural proteins: S1, S2, envelope (E), membrane (M), nucleocapsid (N), and the following ORFs: 3a, 3b, 6, 7a, 7b, and 8 (n = 114; tested in singlets) for each individual/time point. Each sample that is positive (MIMOSA) for at least 1 SARS-CoV-2 antigen is indicated by a solid circle, whereas samples that are negative for all of the SARS-CoV-2 antigens at that time point are indicated by open triangles. The bold black line represents the median fitted curve from a nonlinear mixed effects model of post-day 30 responses among those with a positive response to the antigen(s) under consideration at [3]1 time point; $t_{1/2}$ shown is the median half-life estimated from the median slope, with 95% CI [92, 417].

(B) The proportion of SARS-CoV-2-specific CD8+ T cells by memory phenotype over time: effector memory (EM; CCR7- CD45RA-), T_{EMRA} (CCR7- CD45RA+), and central memory (CM; CCR7+ CD45RA-). Analyses were restricted to positive responders.

(C and D) Polyfunctionality of SARS-CoV-2-specific CD8 T cells at (C) 21–60 days post symptom onset (median, 30 days) and (D) >180 days median post symptom onset (median, 203 days). Percentages of cytokine expressing CD8+ T cells are background subtracted and only subsets with detectable T cells are displayed. Data shown were restricted to positive responders and a single data point per individual per time frame. All CD8+ T cell subsets were also evaluated for expression of IL-4, IL-5, IL-13, and IL-17 and were found to be negative.

(E) The bar graphs indicate the proportion of COVID-19 convalescent patients who had a positive CD8+ T cell response to the individual SARS-CoV-2 stimulations.

(F) The fraction of the total SARS-CoV-2 responding CD8+ T cells per subject that are specific for each peptide pool.

severity (Figure 7A). Neutralizing antibody titers and IgG antibody responses to nucleocapsid increased 1.35-fold and 1.25-fold, respectively, with each decade of age and the same disease severity (95% *Cis* [1.19, 1.54] and [1.08, 1.43], p values < 0.003). Similarly, increased age positively correlated with increased frequencies of spike and RBD-specific IgG+ memory

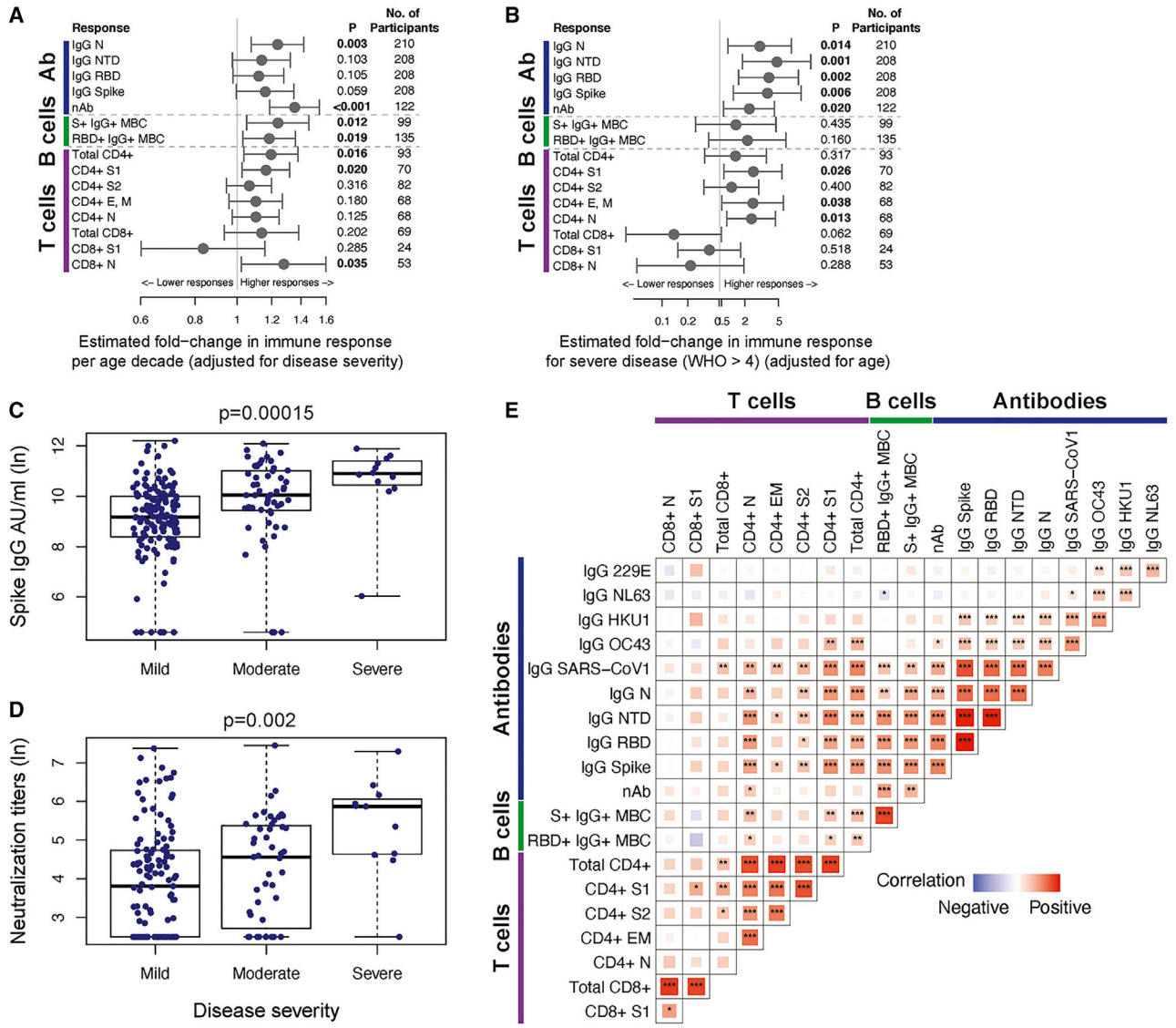

Figure 7. Correlations between SARS-CoV-2-specific immune responses and assessment of covariates

(A) The forest plot depicts the estimated fold-change in the level of each immune response per decade of age, with 95% Wald-based CIs and p values.

(B) The forest plot shows the estimated fold-change in the level of each immune response for severe (WHO score >4) versus non-severe (WHO score £4) disease, with 95% Wald-based CIs and p values. S1 CD8+ T cell responses compared moderate-severe (WHO score >2) to mild (WHO score £2) disease as there were no participants with severe disease with at least one positive S1 CD8+ T cell response post-day 30. Estimates in (A) and (B) are from mixed effects models of post-day 30 (B and T cell responses) or post-day 42 (antibody responses) among responders that account for fixed effects of age and disease severity on the level of immune response.

(C and D) Univariate assessment of disease severity on the magnitude of (C) spike IgG antibodies and (D) SARS-CoV-2 neutralizing antibodies at day 120 is shown for mild (WHO score: 0-2), moderate (WHO score: 3-4), and severe disease (WHO score: 5+); p values from one-way ANOVA.

(E) The heatmap shows Spearman correlations between critical SARS-CoV-2 memory immune responses (day 30 B and T cell responses and day 180 antibody responses) with significance levels: *p < 0.05, **p < 0.01, and ***p < 0.001. The tile size and color intensity correspond to the absolute value of the Spearman rank correlation coefficient, with red or blue indicating a positive or negative correlation, respectively. Day 30, 42, and 180 immune responses were estimated from mixed effects models of the longitudinal SARS-CoV-2 binding antibodies, SARS-CoV-2 neutralizing antibodies, CD4+ and CD8+ T cell responses, and B cell responses.

B cells, with 1.19- to 1.24-fold higher responses per decade of age (p values < 0.02; Figure 7A), accounting for disease severity. Increased age also correlated with higher SARS-CoV-2 and S1-specific CD4+ T cell responses (1.16- to 1.20-fold increase by decade of age, p values < 0.02) and N-specific CD8+ T cell responses (1.24-fold increase by decade of age, p = 0.039) accounting for disease severity (Figure 7A).

Since the cohort included primarily persons with mild-to-moderate COVID-19, we had limited ability to assess the relationship of severe disease and SARS-CoV-2 immune responses,

especially among the cellular responses. However, we found that after accounting for age, severe disease (WHO score >4) was associated with higher IgG antibodies to nucleocapsid, spike, RBD, and NTD (Figures 7B and 7C), and SARS-CoV-2 neutralization titers (Figure 7D). Severe disease was also associated with 2.30- to 2.46-fold higher S1, E and/or M, and nucleocapsid-specific CD4+ T cells (all p values < 0.05; Figure 7B). We found no significant relationships between gender and the immune responses evaluated, apart from 1.66-fold higher IgG NTD responses antibodies among males compared to females, after accounting for age and disease severity (95% CI [1.08, 2.55], p = 0.022). In all, our analyses suggest that there are synergistic but also independent mechanisms driving higher adaptive immune responses in COVID-19 patients who are older and/or who experienced more severe disease.

Early SARS-CoV-2 B and T cell responses correlated with durable spike and RBD IgG antibody binding and neutralization titers

We assessed correlations between SARS-CoV-2-specific immune responses using the individual-level models to interpolate the magnitude of responses for each COVID-19 patient at early (day 30) or later (day 180) convalescent time points (Figure 7E). We found that durable serum neutralization titers correlated with the magnitude of IgG+ binding antibodies to spike, NTD and RBD at day 180 each (day 180; Spearman R = 0.62, 0.61, and 0.61, respectively; all p values < 0.0001). Similarly, the frequency of RBD+ IgG+ memory B cells at day 30 correlated with the maintenance of RBD+ IgG antibodies (day 180; Spearman R = 0.53, p < 0.0001) and neutralization antibody titers (day 180; Spearman R = 0.48, p < 0.0001). We also observed that the magnitude of S1-specific CD4+ T cells at day 30 correlated with durable IgG antibodies against spike (day 180; Spearman R = 0.56, p < 0.0001), NTD (Spearman R = 0.62, p < 0.0001), and RBD (Spearman R = 0.47, p = 0.0002) (Figure 7E). These findings are consistent with early SARS-CoV-2 memory B cells and CD4+ T cells supporting the generation of durable antibody responses.

DISCUSSION

Establishing immune memory is essential in the defense against SARS-CoV-2 infection. To end the COVID-19 pandemic, it is critical to know how long immunity against SARS-CoV-2 will persist after infection and whether it will be sufficient to prevent new infections and severe disease in years to come. Identifying, in-depth, the adaptive immune components leading to recovery and modeling the trends of each response was enabled by the longitudinal sampling of a large number of COVID-19 patients. Here, we show that most convalescent COVID-19 patients mount durable antibodies, B cells, and T cells specific for SARS-CoV-2 up to 250 days, and the kinetics of these responses provide an early indication for a favorable course ahead to achieve long-lived immunity. Because the cohort will be followed for 2–3 more years, we can build on these results to define the progression to long-lived immunity against this novel human coronavirus, which can guide rational responses when future outbreaks occur.

The hallmark of the initial immune defense against SARS-CoV-2 is the emergence of antibodies recognizing the SARS-CoV-2 spike protein, including the RBD and NTD components of the S1 subunit, during the early phase of viral replication. These antibodies are likely secreted from plasmablasts rapidly generated from B cells that are activated upon their first encounter with the pathogen spike antigen. The brisk rise over the first month of infection, followed by a fast decline of the circulating spike IgG and IgA antibodies, is a consistent finding and likely explained by the disappearance of the short-lived plasmablasts. These events occur even sooner for the spike IgM and nucleocapsid antibodies.

Some antibodies that bind to specific epitopes on the spike RBD and NTD can block SARS-CoV-2 infection of respiratory epithelial cells by inhibiting the interactions of the viral spike with the ACE2 receptor.[17-20] Thus, as expected, the early rise and decline of antibodies neutralizing live SARS-CoV-2 were similar to the kinetics of antibodies binding the spike and RBD protein. The striking finding is the bi-phasic curve of the spike-specific binding and neutralizing antibody responses when analyzed with the power law model, which provides a better fit for the antibody kinetics after the peak response.[21] This bi-phasic decline accords with other recently published observations on SARS-CoV-2 serological kinetics.[22,23] With sampling data extended to 250 days, we were able to detect a slowing of the decay of these functional antibodies toward a plateau level, suggestive of the generation of longer-lived plasma cells, and durable antibody responses. The importance of these observations is that following recovery, neutralizing antibodies may persist, albeit at low levels, and may act as the first line of defense against future encounters of SARS-CoV-2 and possibly related human coronaviruses.

Another interesting finding of this investigation is the remarkably stable antibody responses among the pre-pandemic and COVID-19 patients to the common human coronaviruses that are acquired in children and adults. These data are most consistent with the generation of long-lived plasma cells and refute the current notion that these antibody responses to human coronaviruses are short lived. Moreover, the COVID-19 patients mounted increased IgG antibody responses to SARS-CoV-1, a related pathogen that none likely had experienced previous exposure to. This finding is consistent with the booster response of SARS-CoV-1 neutralizing antibodies that we recently observed following SARS-CoV-2 mRNA vaccination.[3,24] Taken together, these results may have implications for a broader strategy for vaccines targeting multiple betacoronaviruses.

The durable antibody responses in the COVID-19 recovery period are further substantiated by the ongoing rise in both the spike and RBD memory B cell responses after over 3–5 months before entering a plateau phase over 6–8 months. Persistence of RBD memory B cells has been noted.[25-27] We presume this may be explained by sustained production of memory B cells in germinal centers of lymph nodes draining the respiratory tract in the early months, followed by the memory B cell redistribution into the circulation as the germinal centers begin to recede. Thus, the induction and maintenance of memory B cells and, over time, long-lived plasma cells, will continue to furnish higher affinity antibodies if re-exposures occur.

In contrast to spike memory B cell kinetics, SARS-CoV-2-specific CD4+ and CD8+ memory T cells each peak early, within the first month, but then slowly decline over the next 6–7 months. Central memory Th1-type CD4+ T cells dominate throughout the early infection and recovery period. However, the CD8+ T cells exhibit a predominant effector memory phenotype early that transitions to those effector memory cells re-expressing CD45RA, maintaining expression of antiviral cytokines and effector functions that have been shown to provide protective immunity against other viral pathogens. We also provide clear evidence that the CD4+ T cells mount a broader antigen-specific response across the structural and accessory gene products, whereas the CD8+ T cells are predominantly nucleocapsid specific and spike-specific responses are substantially lower in frequency.

Our study demonstrates the considerable immune heterogeneity in the generation of potentially protective response against SARS-CoV-2, and by focusing on the dynamics and maintenance of B and T cell memory responses, we were able to identify features of these early cellular responses that can forecast the durability of a potentially effective antibody response. The ability to mount higher frequencies of RBD-specific memory IgG+ B cells early in infection was the best indicator for a durable RBD-specific IgG antibody and neutralizing antibody response. In addition, higher frequency CD4+ T cells were associated with stronger spike IgG and neutralizing antibody responses. However, the induction and peak response of SARS-CoV-2-specific CD8+ T cells occurs independently to these antibody responses. Interestingly, while it has been widely reported that age correlates with COVID-19 disease severity, we found that age and disease severity were independent co-variates associated with the magnitude of both SARS-CoV-2-specific CD4+ T cell and humoral SARS-CoV-2 immunity, but not with the magnitude of CD8+ T cell responses. In the case of T cells, whether the T cell differences are related to the frequencies or specificities of pre-existing coronavirus CD4+ and CD8+ T cell immunity will require additional future analysis.

The COVID-19 pandemic remains a global public health threat after 1 year of overwhelming disruption and loss. Overcoming the challenges to end the pandemic is accentuated by the recognition that SARS-CoV-2 can undergo rapid antigenic variation that may lower vaccine effectiveness in preventing new cases and progression to severe disease.[24,28,29] Our findings show that most COVID-19 patients induce a wide-ranging immune defense against SARS-CoV-2 infection, encompassing antibodies and memory B cells recognizing both the RBD and other regions of the spike, broadly-specific and polyfunctional CD4+ T cells, and polyfunctional CD8+ T cells. The immune response to natural infection is likely to provide some degree of protective immunity even against SARS-CoV-2 variants because the CD4+ and CD8+ T cell epitopes will likely be conserved. Thus, vaccine induction of CD8+ T cells to more conserved antigens such as the nucleocapsid, rather than just to SARS-CoV-2 spike antigens, may add benefit to more rapid containment of infection as SARS-CoV-2 variants overtake the prevailing strains.

Limitations of the study

Our study evaluates COVID-19 patients only up to 8 months and requires models to estimate immune response half-lives thereafter. Because our longitudinal study will extend beyond 2 years, we can corroborate our models with subsequent experimental data on the persistence of immune memory. Our study population was primarily outpatients with mild-to-moderate COVID-19 and thus we were unable to evaluate immune memory in those with the extreme presentations, both asymptomatic and severe COVID-19. However, mild-moderate illness accounts for >80% of COVID-19 cases[30], highlighting the relevance of our findings over time.

STAR★METHODS

Detailed methods are provided in the online version of this paper and include the following:

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SUPPLEMENTAL INFORMATION

Supplemental information can be found online at https://doi.org/10.1016/j.xcrm.2021.100354.

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AUTHOR CONTRIBUTIONS

M.J.M and R. Ahmed conceived the study. M.J.M., S.E., J.C., E.J.A., A.K.M, N.R., and J.O.K. established the cohort and recruited the participants. S.L.L., M.P.L., C.W.D., M.P.G., S.G., K.A.S., G.M., C.N., V.V.E., L.L., and D.S.S. conducted serological assays and related analyses. H.A., V.I.Z., B.P., and Z.M. conducted formal statistical analyses and modeling. K.W.C., R.W., and L.E.N. planned, performed, and analyzed antigen-specific B cell flow cytometry. S.C.D., K.W.C., and S.F. conceived, supervised, performed, and analyzed T cell experiments. V.E.E, K.F., and L.L. performed FRNT assays. K.W.C., S.L.L., and Z.M. drafted the original manuscript; M.J.M., M.S.S., and R. Ahmed edited the manuscript. All authors read and approved the manuscript. M.J.M., R.A, J.W., and M.S.S. secured funds and supervised the project.

DECLARATION OF INTERESTS

The authors declare no competing interests.

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STAR★METHODS

KEY RESOURCES TABLE

REAGENT or RESOURCE	SOURCE	IDENTIFIER
Antibodies		
Mouse Anti-Human CD3/BV510	BD Biosciences	564713; RRID:AB_2738909
Mouse Anti-Human CD14/BV510	BD Biosciences	563079; RRID:AB_2737993
Mouse Anti-Human CD56/BV510	BD Biosciences	563041; RRID:AB_2732786
Mouse Anti-Human CD19/BUV395	BD Biosciences	563549; RRID:AB_2738272
Mouse Anti-Human CD20/BUV737	BD Biosciences	612849; RRID:AB_2870169
Mouse Anti-Human CD21/PE-Cy7	BD Biosciences	561374; RRID:AB_10681717
Mouse Anti-Human CD27/BV605	BD Biosciences	302830; RRID: AB_2561450
Mouse Anti-Human CD38/BB700	BioLegend	566445; RRID:AB_2744375
Mouse Anti-Human IgA/VioBlue	Miltenyi Biotec	130-114-005; RRID:AB_2733958
Mouse Anti-Human IgD/BV650	BD Biosciences	740594; RRID:AB_2740295
Mouse Anti-Human IgG/BV786	BD Biosciences	564230; RRID:AB_2738684
Mouse Anti-Human IgM/PE-Dazzle 594	BioLegend	314530; RRID:AB_2566483
Streptavidin (PE)	Invitrogen	S21388; RRID:AB_2892541
Streptavidin (AF488)	Invitrogen	S32354; RRID:AB_2315383
Streptavidin (AF647)	Invitrogen	S32357; RRID:AB_2892542
Live/Dead Fixable Aqua Stain	Invitrogen	L34957
Fixable Viability Dye/eFluor 450	Invitrogen	65-0863
Mouse Anti-Human CD14/BUV661	BD Biosciences	741684; RRID:AB_2868407
Mouse Anti-Human CD19/BUV563	BD Biosciences	612916; RRID:AB_2870201
Mouse Anti-Human CD16/BV570	BioLegend	302036; RRID:AB_2632790
Mouse Anti-Human CD56/BV750	BioLegend	362556; RRID:AB_2801001
Mouse Anti-Human CD3/APC-Fire750	BioLegend	300470; RRID:AB_2629689
Mouse Anti-Human CD4/BV480	BD Biosciences	566104; RRID:AB_2739506
Mouse Anti-Human CD8/BUV805	BD Biosciences	612889; RRID:AB_2833078
Mouse Anti-Human CD197(CCR7)/BV605	BioLegend	353224; RRID:AB_2561753
Mouse Anti-Human CD45RA/BUV496	BD Biosciences	750258; RRID:AB_2874456
Mouse Anti-Human CD25/BV650	BD Biosciences	563719; RRID: AB2744337
Rat Anti-Human FOXP3/PE-Cy5.5	Invitrogen	35-4776-42; RRID:AB_11218682
Mouse Anti-Human CD32/PE-Dazzle	BioLegend	303218; RRID:AB_2716072
Mouse Anti-Human CD65/BV711	BioLegend	305042; RRID:AB_2800778
Mouse Anti-Human CD183/PE-Cy5	BD Biosciences	551128; RRID:AB_394061
Mouse Anti-Human CD196 (CCR6)/BV786	BD Biosciences	563704; RRID:AB_2738381
Rat Anti-Human CD294 (CRTH2)/PE	BioLegend	350106; RRID:AB_10900060
Mouse Anti-Human IFN-g/V450	BD Biosciences	560371; RRID:AB_1645594
Rat Anti-Human IL-2/APC	BioLegend	500310; RRID:AB_315097
Mouse Anti-Human TNF/BUV395	BD Biosciences	563996; RRID:AB_2738533
Mouse Anti-Human IL-17A/PE-Cy7	BioLegend	512315; RRID:AB_2295923
Rat Anti-Human IL-4/BB700	BD Biosciences	Custom
Rat Anti-Human/Anti-Mouse IL-5/BB630	BD Biosciences	Custom
Rat Anti-Human IL-13/BV421	BD Biosciences	Custom
Mouse Anti-Human CD154 (BUV737)	BD Biosciences	748983; RRID:AB_2873383
Mouse Anti-Human Granzyme B/AF700	BD Biosciences	560213; RRID:AB_1645453
Mouse Anti-Human Perforin/FITC	BD Biosciences	353310; RRID:AB_2571967
Mouse Anti-Human Ki-67/BB660	BD Biosciences	Custom

(*Continued on next page*)

Continued

REAGENT or RESOURCE	SOURCE	IDENTIFIER
Bacterial and virus strains		
icSARS-CoV-2-mNG	Xie et a.	N/A
Chemicals, peptides, and recombinant proteins		
SARS-CoV-2 Spike peptides	Biosynthesis	Custom
SARS-CoV-2 E, M, N and ORF peptides	Genscript	Custom
SARS-CoV-2 Spike protein (S6P)	Fred Hutchinson Cancer Research Center	Custom
SARS-CoV-2 RBD protein	Fred Hutchinson Cancer Research Center	Custom
Methylcellulose	Sigma-Aldrich	M0512-250G
TrueBlue Peroxidase Substrate	KPL	5510-0050
Critical commercial assays		
V-PLEX COVID-19 Coronavirus Panel 2 (IgG) Kit	Meso Scale Discovery	K15369U
V-PLEX COVID-19 Coronavirus Panel 2 (IgA) Kit	Meso Scale Discovery	K15371U
V-PLEX COVID-19 Coronavirus Panel 2 (IgM) Kit	Meso Scale Discovery	K15370U
Experimental models: Cell lines		
VeroE6 C1008 cells	ATCC	Cat# CRL-1586; RRID:CVCL_0574
Software and algorithms		
FlowJo	BD Biosciences	V9.9.4
R	R Foundation for Statistical Computing	V3.6.1
GraphPad Prism	GraphPad	V7, 8 and 9
Viridot	Katzelnick et al.	https://github.com/leahkatzelnick/Viridot
Monolix	Lixoft	MonolixSuite2019R1
Other		
ELISPOT reader	Immunospot	CTL ImmunoSpot S6 Universal Analyzer

RESOURCE AVAILABILITY

Lead contact

Further information and requests for resources and reagents should be directed to and will be fulfilled by the lead contact, M. Juliana McElrath (jmcelrat@fredhutch.org).

Materials availability

This study did not generate new unique reagents.

Data and code availability

The underlying data for this paper will be shared by the lead contact upon request without restriction.

EXPERIMENTAL MODEL AND SUBJECT DETAILS

Study populations

Two longitudinal COVID-19 cohort studies at Fred Hutchinson Cancer Research Center (Seattle, Washington) and Emory University (Atlanta, Georgia) began after receiving institutional review board approvals (IRB 10440, IRB 00001080 and IRB00022371). Adults ^{3}18 years were enrolled who met eligibility criteria for SARS-CoV-2 infection and provided informed consent. Study participants provided medical history of co-morbidities, presentation of SARS-CoV-2 infection onset and disease course, and peripheral blood at initial and follow up visits for analysis of serum antibody and cellular immune responses. Additional longitudinal archived sera and PBMC from pre-pandemic study populations from Emory and Seattle served as controls for the immune assays.

The Atlanta study population included adult volunteers over the age of 18 who were diagnosed with COVID-19 by a commercially available SARS CoV-2 PCR assay, rapid antigen test, or clinical syndrome only (later confirmed with serology) due to limited SARS-CoV-2 testing during the early period of the pandemic. Ambulatory participants were recruited through local advertisements,

internet-based avenues (such as social media, listserves), COVID-19 testing sites, and primary care clinics. Hospitalized patients were identified through SARS-CoV-2 testing. Informed consent was obtained from all participants prior to conduct of study procedures. Initial acute peripheral blood samples were collected from hospitalized patients at the time of enrollment. Convalescent samples from hospitalized patients were collected when the patients were able to return for a visit to the clinical research site at the next study visit. Serial peripheral blood samples were collected starting at about 30 days after the onset of COVID-19 symptoms and/or after PCR positivity for SARS-CoV-2. Thereafter, samples were collected at 3, 6, and 9 months. The study is ongoing with expected completion of sample collection from participants in February 2023. Participants were excluded if they were immunocompromised, HIV positive, had active hepatitis B or C virus infection, used immunosuppressive drugs for 2 weeks or more in the preceding 3 months, received blood products or immune globulin 42 days prior to enrollment, received convalescent COVID-19 plasma, or were pregnant or breast feeding. We report on 110 participants to date, of which 73% were diagnosed by SARS-CoV-2 PCR, the remaining were diagnosed by rapid antigen test or serology. Demographic features of the participants are as follows: median age was 48; 45% were male; the majority (80%) were white, 11% Black/African American, 6% Asian, and 8% were Hispanic/Latinx ethnicity. The most frequent co-morbid conditions were hypertension, obesity, heart disease and diabetes mellitus. The most frequent COVID-19 symptoms were myalgia/fatigue, fever, cough, headache, loss of smell and taste (Table S1). Hospitalized patients were older, with a median age of 56; a higher percentage were Black/African American (27%); and 100% had fever.

Longitudinal pre-pandemic sera samples from Emory were collected from individuals participating in a yellow fever vaccine study from 2014-2016 or an influenza vaccine study from 2015-2018[15,31]. Data were included for analysis of binding antibody responses and are presented as days post-irrelevant (yellow fever) vaccination. The study was approved by the Emory University IRB and donors were enrolled after providing written informed consent.

The Seattle COVID-19 Cohort study participants were recruited from the Seattle metropolitan area by social media advertisements, partnership with the local emergency medical service and by word of mouth. Study participants were screened and enrolled by the Seattle Vaccine Trials Unit staff. Eligibility criteria included adults at risk for SARS-CoV-2 infection or those diagnosed with COVID-19 by a commercially available SARS-CoV-2 PCR assay or blood antibody test and willing to have at least four blood draws collected over one year. Exclusion criteria included pregnancy and inability to donate blood.

Informed electronic consent was obtained from all Seattle participants during a screening phone call with study clinical staff. Interested participants were screened, consented and medical history and COVID-19 illness onset date and symptoms collected. Participants undiagnosed with COVID-19 had a nasopharyngeal (NP) swab collected and tested for SARS-CoV-2 via an FDA-approved PCR test and blood was collected for SARS-CoV-2 antibody (Abbott) and study assays. Those with either a positive PCR or antibody test were asked to return for future blood draws. Those who tested negative were asked to return as controls for the positive cohort and in case they tested positive in the future. Participants with a positive test prior to study enrollment or those diagnosed in study were asked to provide blood donation at approximately 7 days, 2 weeks, 1, 2, 3, 4, 6, 9- and 12-months post symptom onset. After completing one year of study, participants will be given the option of continuing the longitudinal study for up to two or more years. At each study visit, participant symptoms and medical history is updated. Those with COVID-19 symptoms after enrollment in all groups are offered a nasopharyngeal swab PCR SARS-CoV-2 test.

As of October 2020, 805 individuals have contacted the Seattle COVID-19 cohort study and 425 have enrolled. This includes 281 negative and 144 SARS-CoV-2 positive participants. Reasons for not enrolling include lack of interest, not meeting the eligibility criteria, inability to travel to blood draw location and inability to collect study blood. No participants have terminated from the study. Study enrollment and follow-up remains ongoing. Samples from SARS-CoV-2 negative subjects were included in B and T cell assays as 'contemporaneous' negative controls.

Peripheral blood mononuclear cells (PBMC) were obtained from HIV-1 seronegative donors who were recruited at the Seattle Vaccine Trials Unit before 2019 as part of the study "Establishing Immunologic Assays for Determining HIV-1 Prevention and Control." All participants signed informed consent, and the Fred Hutchinson Cancer Research Center IRB (Seattle, WA, USA) institutional human subjects review committee approved the protocol prior to study initiation. Pre-pandemic samples from this cohort were used as assay controls in B and T cell assays.

METHOD DETAILS

PBMC processing

PBMC for cellular assays were isolated by density centrifugation and cryopreserved from ACD-anticoagulated whole blood within eight h of venipuncture, as described previously [32]. Sera were also processed and cryopreserved within 4 h after collection.

Antibody binding assay

Antibody binding titers were measured using a multiplex plate coated with the SARS-CoV-2 spike, SARS-CoV-2 spike receptor binding domain, SARS-CoV-2 spike N-terminal domain, SARS-CoV-2 nucleocapsid, SARS-CoV-1 spike, 229E spike, NL63 spike, HKU1 spike, and OC43 spike proteins (Mesoscale Discovery). Plates were blocked with 150ml/well with 5% bovine serum albumin in phosphate buffered saline (PBS) and shaken at 700 RPM at room temperature for at least 30 min. Plates were washed 3 times with 150ml/well 0.05% Tween-20 in PBS. Serum and plasma samples were added to the plate at dilutions between 1:500 and 1:50,000 and shaken at 700 RPM at room temperature for 2 h. Following a wash, plates were incubated with 50ul/well of Sulfo-Tag anti-human

IgG, IgA, or IgM detection antibody and shaken at 700RPM at room temperature for 1 h. After a subsequent wash, 150ml/well of MSD GOLD read buffer was added to the plate and plates were immediately read on the MSD instrument to measure light intensity. Antibody levels are reported as arbitrary units/mL (AU/mL) based on normalization to a standard curve.

Viruses and cell lines

VeroE6 cells were obtained from ATCC (clone E6, ATCC, #CRL-1586) and cultured in complete DMEM medium consisting of 1 × DMEM (VWR, #45000-304), 10% FBS, 25mM HEPES Buffer (Corning Cellgro), 2mM L-glutamine, 1mM sodium pyruvate, 1 × Non-essential Amino Acids, and 1 × antibiotics. The infectious clone SARS-CoV-2 (icSARS-CoV-2-mNG), derived from the 2019-nCoV/USA_WA1/2020 strain, was propagated in VeroE6 cells and sequenced [33,34].

Focus reduction neutralization test

Neutralization assays with SARS-CoV-2 virus were performed as previously described [33-35]. Plasma/serum were serially diluted (three-fold) in serum-free Dulbecco's modified Eagle's medium (DMEM) in duplicate wells and incubated with 100–200 FFU infectious clone derived SARS-CoV-2-mNG virus at 37°C for 1 h [33]. The antibody-virus mixture was added to VeroE6 cell (C1008, ATCC, #CRL-1586) monolayers seeded in 96-well blackout plates and incubated at 37°C for 1 h. Post-incubation, the inoculum was removed and replaced with pre-warmed complete DMEM containing 0.85% methylcellulose. Plates were incubated at 37°C for 24 h. After 24 h, methylcellulose overlay was removed, cells were washed twice with PBS and fixed with 2% paraformaldehyde in PBS for 30 min at room temperature. Following fixation, plates were washed twice with PBS and foci were visualized on a fluorescence ELISPOT reader (CTL ImmunoSpot S6 Universal Analyzer) and enumerated using Viridot [36]. The neutralization titers were calculated as follows: 1 - (ratio of the mean number of foci in the presence of sera and foci at the highest dilution of respective sera sample). Each specimen was tested in two independent assays performed at different times. The FRNT-mNG$_{50}$ titers were interpolated using a 4-parameter nonlinear regression in GraphPad Prism 8.4.3. Samples with an FRNT-mNG$_{50}$ value that was below the limit of detection were plotted at 20.

Spike and RBD memory B cell flow cytometry assays

Fluorescent SARS-CoV-2-specific S6P[37] (provided by Roland Strong, Fred Hutchinson Cancer Research Center, Seattle, WA) and RBD (provided by Leonidas Stamatatos, Fred Hutchinson Cancer Research Center, Seattle, WA) probes were made by combining biotinylated protein with fluorescently labeled streptavidin (SA). The S6P probes were made at a ratio of 1:1 molar ratio of trimer to SA. Two S6P probes, one labeled with AlexaFluor488 (Invitrogen), one labeled with AlexaFluor647 (Invitrogen), were used in this panel in order to increase specificity of the detection of SARS-CoV-2-specific B cells. The RBD probe was prepared at a 4:1 molar ratio of RBD monomers to SA, labeled with R-phycoerythrin (Invitrogen). Cryopreserved PBMCs from SARS-CoV-2-convalescent participants and a pre-pandemic SARS-CoV-2-naive donor were thawed at 37°C and stained for SARS-CoV-2-specific memory B cells as described previously[19] with a panel of fluorescently-labeled antibodies (see Key Resource Table). Cells were stained first with the viability stain (Invitrogen) in PBS for 15 min at 4°C. Cells were then washed with 2% FBS/PBS and stained with a cocktail of the three probes for 30 min at 4°C. The probe cocktail was washed off with 2% FBS/PBS and the samples were stained with the remaining antibody panel and incubated for 25 min at 4°C. The cells were washed two times and resuspended in 1% paraformaldehyde/1 × PBS for collection on a LSR II or FACSymphony flow cytometer (BD Biosciences). Data was analyzed in Flow Jo version 9.9.4.

Intracellular cytokine staining (ICS) assay

Flow cytometry was used to examine SARS-CoV-2-specific CD4+ and CD8+ T cell responses using a validated ICS assay. The assay was similar to a published report [5,38,39] and the details of the staining panel are included in the Key Resource Table. Peptide pools covering the structural proteins of SARS-CoV-2 were used for the six-h stimulation. Peptides matching the SARS-CoV-2 spike sequence (316 peptides, plus 4 peptides covering the G614 variant) were synthesized as 15 amino acids long with 11 amino acids overlap and pooled in 2 pools (S1 and S2) for testing (BioSynthesis). All other peptides were 13 amino acids overlapping by 11 amino acids and were synthesized by GenScript. The peptides covering the envelope (E), membrane (M) and nucleocapsid (N) were initially combined into one peptide pool, but the majority of the assays were performed using a separate pool for N and one that combined only E and M. Several of the open reading frame (ORF) peptides were combined into two pools: ORF 3a and 6, and ORF 7a, 7b and 8. All peptide pools were used at a final concentration of 1 mg/mL for each peptide. As a negative control, cells were not stimulated, only the peptide diluent (DMSO) was included. As a positive control, cells were stimulated with a polyclonal stimulant, staphylococcal enterotoxin B (SEB). Cells expressing IFN-g and/or IL-2 and/or CD154 was the primary immunogenicity endpoint for CD4+ T cells and cells expressing IFN-g was the primary immunogenicity endpoint for CD8+ T cells. The overall response to SARS-CoV-2 was defined as the sum of the background-subtracted responses to each of the individual pools. A sample was considered positive for CD4+ or CD8+ T cell responses to SARS-CoV-2 if any of the CD4+ or CD8+ T cell responses to the individual peptide pool stimulations was positive. Positivity was determined using MIMOSA [40]. The total number of CD4+ T cells must have exceeded 10,000 and the total number of CD8+ T cells must have exceeded 5,000 for the assay data to be included in the analysis.

QUANTIFICATION AND STATISTICAL ANALYSIS

Binding and neutralizing antibody responses

Mixed effects exponential and power law models were used to analyze waning of antibody (day 42 to day 263 post symptom onset). For binding antibody analyses, antibody (Ab) was natural log transformed, yielding linear equations of the form ln(Ab) = a+b*(day-42) and ln(Ab) = a+b*ln(day/42) for the exponential and power law models, respectively, and fit using the lmer function (lme4 package) in R. Models included population level fixed effects and individual level random effects for intercept and slope and covariance between the random effects. Simplified models – with random effects only for intercept – were also fit. Neutralization antibody data were analyzed in Monolix (Lixoft). For analysis in Monolix, the exponential and power law models were formulated as ordinary differential equations, dAb/dt = k*Ab and dAb/dt = k*Ab/t, respectively, with antibody at day 42 lognormally distributed and lognormal multiplicative error. Neutralization titers < 20 were treated as left censored. For comparison of models, difference in Akaike information criterion (DAIC) > 4 was considered statistically significant. Models (in R and Monolix) were fit using maximum likelihood. To account for repeated-measures, correlations between antibody binding levels and neutralization titers were calculated using a repeated-measures correlation (rmcorr package) in R [41].

B cell responses

We considered linear mixed effects models for B cell response, y_{ij}, as a function of t_{ij}, the j^{th} time since symptom onset for the i^{th} individual, with random effects for intercept and slope and $t_{ij} > 30$ days for all i, j:

$$\log_e y_{ij} = \beta_{0i} + \beta_{1i} t_{ij} + \varepsilon_{ij}$$

where $\beta_{0i} = \beta_0 + b_i$ and $\beta_{1i} = \beta_1 + c_i$ with (b_i, c_i) iid $\sim N_2(0, \Sigma)$, with

$$\Sigma = \begin{bmatrix} \sigma_b^2 & Cov(b,c) \\ Cov(b,c) & \sigma_c^2 \end{bmatrix}$$

and σ_b^2 and σ_c^2 are the between-person variation in the intercept and slope of log B cell responses respectively, *Cov(b, c)* is the covariance between the intercept and slope, and ε_{ij} iid $\sim N(0, \sigma^2)$. The random effects, b_i and c_i, are each assumed to be independent for different individuals and the within-individual errors ε_{ij} are assumed to be independent for different *i, j* and to be independent of the random effects. The function lme from the R package nlme was used to fit the models.

T cell responses

Longitudinal analyses of CD4+ and CD8+ T cell responses were performed for individuals with a positive response for at least one time point 30 days after symptom onset. The MIMOSA (Mixture Models for Single-Cell Assays) [40] model incorporated cell count and cell proportion information to define a positive CD4+/CD8+ T cell response by ICS by comparing peptide pools stimulated cells and unstimulated negative controls. This method assumed a common distribution for cytokine positive CD4+/CD8+ T cells in stimulated and unstimulated samples in non-responders, resulting in paired differences that were zero on average. In contrast, for responders, the distribution of the proportion of cytokine positive cells for stimulated samples was assumed to be greater than for unstimulated samples, resulting in paired differences that were greater than zero on average. The MIMOSA method modeled this structure through a Bayesian hierarchical mixture model framework. One component (or distribution) of the model represented the responders, and the other component modeled the non-responders. The parameters defining these distributions, as well as the probabilities that each ICS response was either a responder or non-responder, were estimated from the observed data. This sharing of information across SARS-CoV-2 responders and non-responders increased the sensitivity and specificity to make positivity calls [42]. Responses with probability of response > 0.999 were considered positive responders.

We considered nonlinear mixed effects models for T cell response, y_{ij}, as a function of t_{ij}, the j^{th} time since symptom onset for the i^{th} individual, with random effects for intercept and slope and $t_{ij} > 30$ days for all i, j:

$$\log_e y_{ij} = \beta_{0i} - \exp(\beta_{1i}) t_{ij} + \varepsilon_{ij}$$

where $\beta_{0i} = \beta_0 + b_i$ and $exp(\beta_{1i}) = exp(\beta_1 + c_i)$ with (b_i, c_i) iid $\sim N_2(0, \Sigma)$, with

$$\Sigma = \begin{bmatrix} \sigma_b^2 & 0 \\ 0 & \sigma_c^2 \end{bmatrix}$$

and σ_b^2 and σ_c^2 are the between-person variation in the intercept and slope of log T cell responses respectively, and ε_{ij} iid $\sim logNormal(0, \sigma^2)$. The random effects, b_i and c_i, are each assumed to be independent for different individuals and the within-individual errors ε_{ij} are assumed to be independent for different *i, j* and to be independent of the random effects. The function nlme from the R package nlme was used to fit the models.

Diagnostic plots of residuals were examined to assess validity of the model assumptions.

Age at enrollment, gender, and disease severity (WHO score > 4) were included as covariates in the mixed effects models to assess their association with each immune response.

Individual-level estimates at days 30 (T and B cell responses), day 42 (binding and neutralizing antibody responses) and day 180 (all responses) were obtained from the mixed effects models described above. Spearman rank correlations, Wald-based two-sided 95% confidence intervals and p values were reported.

Generalized estimating equations (GEE), with an independence working covariance matrix, were used to confirm the results of the covariate assessments for B and T cell responses from the mixed effects models. Two-tailed P values based on the robust standard error estimates for the covariate coefficients were consistent with the corresponding two-tailed P values for the covariate associations from the mixed effects models.

All tests were two-sided and P values < 0.05 were considered statistically significant unless otherwise noted. Details of specific statistical analyses can be found in the Results section and in the Figure legends.

EXHIBIT E

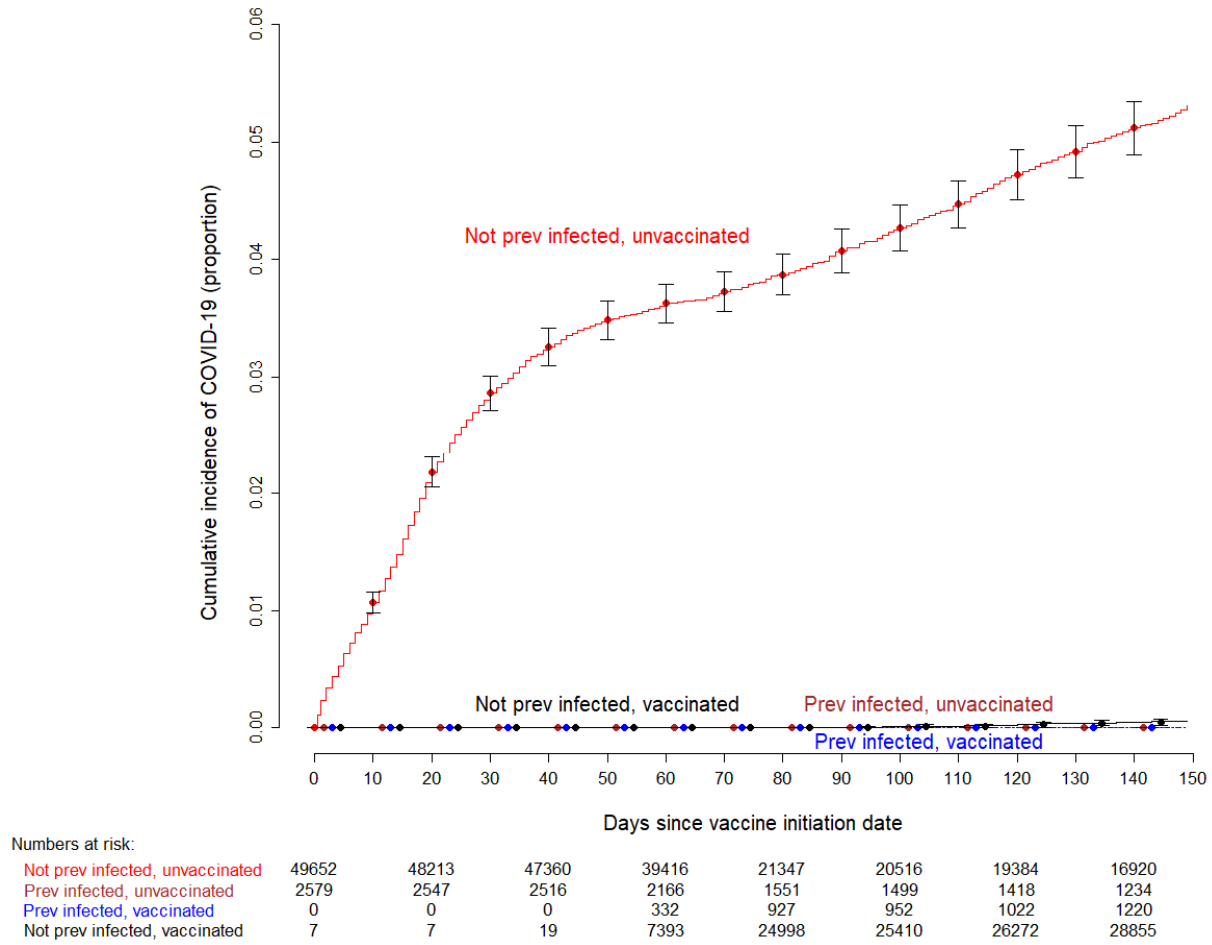

Figure 3. Simon-Makuch plot showing the cumulative incidence of COVID-19 among subjects previously infected and not previously infected with COVID-19, who did and did not receive the vaccine. Curves for the unvaccinated are based on data for those who did not receive the vaccine during the duration of the study, and for those waiting to receive the vaccine. Day zero was Dec 16, 2020, the day vaccination was started in our institution. Error bars represent 95% confidence intervals. Seven subjects who had been vaccinated earlier as participants in clinical trials were considered vaccinated throughout the duration of the study. Twelve subjects who received their first dose in the first week of the vaccination campaign managed to get their second dose three weeks later, and were thus considered vaccinated earlier than 42 days since the start of the vaccination campaign.

EXHIBIT E

Necessity of COVID-19 vaccination in previously infected individuals

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Summary: Cumulative incidence of COVID-19 was examined among 52238 employees in an American healthcare system. COVID-19 did not occur in anyone over the five months of the study among 2579 individuals previously infected with COVID-19, including 1359 who did not take the vaccine.

EXHIBIT E

ABSTRACT

Background. The purpose of this study was to evaluate the necessity of COVID-19 vaccination in persons previously infected with SARS-CoV-2.

Methods. Employees of the Cleveland Clinic Health System working in Ohio on Dec 16, 2020, the day COVID-19 vaccination was started, were included. Any subject who tested positive for SARS-CoV-2 at least 42 days earlier was considered previously infected. One was considered vaccinated 14 days after receipt of the second dose of a SARS-CoV-2 mRNA vaccine. The cumulative incidence of SARS-CoV-2 infection over the next five months, among previously infected subjects who received the vaccine, was compared with those of previously infected subjects who remained unvaccinated, previously uninfected subjects who received the vaccine, and previously uninfected subjects who remained unvaccinated.

Results. Among the 52238 included employees, 1359 (53%) of 2579 previously infected subjects remained unvaccinated, compared with 20804 (42%) of 49659 not previously infected. The cumulative incidence of SARS-CoV-2 infection remained almost zero among previously infected unvaccinated subjects, previously infected subjects who were vaccinated, and previously uninfected subjects who were vaccinated, compared with a steady increase in cumulative incidence among previously uninfected subjects who remained unvaccinated. Not one of the 1359 previously infected subjects who remained unvaccinated had a SARS-CoV-2 infection over the duration of the study. In a Cox proportional hazards regression model, after adjusting for the phase of the epidemic, vaccination was associated with a significantly lower risk of SARS-CoV-2 infection among those not previously infected (HR 0.031, 95% CI 0.015 to 0.061) but not among those previously infected (HR 0.313, 95% CI 0 to Infinity).

Conclusions. Individuals who have had SARS-CoV-2 infection are unlikely to benefit from COVID-19 vaccination, and vaccines can be safely prioritized to those who have not been infected before.

EXHIBIT E

INTRODUCTION

The two FDA-approved (BNT162b2 mRNA [Pfizer-BioNTech] and mRNA-1273 [Moderna]) mRNA vaccines have been shown to be very efficacious in protecting against Severe Acute Respiratory Syndrome (SARS) – associated Coronavirus-2 (SARS-CoV-2) infection [1,2]. The effectiveness of the Pfizer-BioNTech vaccine in a real-world setting has also been shown to be comparable to the efficacy demonstrated in clinical trials [3,4]. Given these, there has been an understandable desire to vaccinate as many people as possible.

The ability to vaccinate a large part of the population is limited by the supply of vaccine. As of March 21, 2021, 78% of 447 million doses of the coronavirus disease 2019 (COVID-19) vaccines that had been deployed had gone to only ten countries [5]. The COVAX initiative was borne out of the recognition that equitable distribution of vaccines worldwide was essential for effective control of the COVID-19 pandemic. However, the reality is that there is great disparity in the availability of vaccines across countries. Countries with limited supplies of vaccine have to prioritize how their supply of vaccines will be allocated within their populations. Criteria used for such prioritization have included profession, age, and comorbid conditions. Data that inform prioritization criteria with help maximize the benefits of whatever vaccine is available.

Observational studies have found very low rates of reinfection among individuals with prior SARS-CoV-2 infection [6–8]. This brings up the question about whether it is necessary to vaccinate previously infected individuals. These studies notwithstanding, there remains a theoretical possibility that the vaccine may still provide some benefit in previously infected persons. A prior large observational study concluded that immunity from natural infection cannot be relied on to provide adequate protection and advocated for vaccination of previously infected individuals [9]. The CDC website recommends that persons previously infected with SARS-CoV-2 still get the vaccine [10]. Despite these recommendations, credible reports of previously infected persons getting COVID-19 are rare. The rationale often provided for getting the COVID-19 vaccine is that it is safer to get vaccinated than to get the disease. This is

EXHIBIT E

certainly true, but it is not an explanation for why people who have already had the disease need to be vaccinated. A strong case for vaccinating previously infected persons can be made if it can be shown that previously infected persons who are vaccinated have a lower incidence of COVID-19 than previously infected persons who did not receive the vaccine.

The purpose of this study was to attempt to do just that, and thereby evaluate the necessity of the COVID-19 vaccine in persons who were previously infected with SARS-CoV-2.

METHODS

Study design

This was a retrospective cohort study conducted at the Cleveland Clinic Health System in Ohio, USA. The study was approved by the Cleveland Clinic Institutional Review Board. A waiver of informed consent and waiver of HIPAA authorization were approved to allow access to personal health information by the research team, with the understanding that sharing or releasing identifiable data to anyone other than the study team was not permitted without additional IRB approval.

Setting

PCR testing for SARS-CoV-2 at Cleveland Clinic began on March 12, 2020, and a streamlined process dedicated to the testing of health care personnel (HCP) was begun shortly thereafter. All employees with a positive SARS-CoV-2 test were interviewed by Occupational Health, with date of onset of symptoms of COVID-19 being one of the questions asked. Vaccination for COVID-19 began at Cleveland Clinic on December 16, 2020. When initially started it was the Pfizer-BioNTech vaccine that was administered, until the Moderna vaccine became available, from which time employees received one or the other. All employees were scheduled to receive their second vaccine dose 28 days after the first one, regardless of which vaccine was given. The employee cohort was chosen for this study because of documentation of their COVID-19 vaccination and of any SARS-CoV-2 infection in the Occupational Health database.

Participants

All employees of the Cleveland Clinic Health System, working in Ohio, on Dec 16, 2020, were screened for inclusion in the study. Those who were in employment on December 16, 2020, were included.

Variables

SARS-CoV-2 infection was defined as a positive nucleic acid amplification test. The date of infection was taken to be the date of onset of symptoms when available, and the date of specimen collection when not. A person was considered vaccinated 14 days after receipt of the second dose of the vaccine (which would have been 42 days after receipt of the first dose of the vaccine for most subjects). For the sake of consistency in the duration assumed for development of natural and vaccine immunity, any person who tested positive for SARS-CoV-2 at least 42 days before the vaccine rollout date, was considered previously infected. Other covariates collected were age, job location, job type (patient-facing or non-patient facing), and job category. The job location variable could be one of the following: Cleveland Clinic Main Campus, regional hospital (within Ohio), ambulatory center, administrative center, or remote location. The job category was one of the following: professional staff, residents/fellows, advance practice practitioners, nursing, pharmacy, clinical support, research, administration, and administration support.

Outcome

The study outcome was time to SARS-CoV-2 infection, the latter defined as a positive nucleic acid amplification test for SARS-CoV-2 on or after December 16, 2020. Time to SARS-CoV-2 infection was calculated as number of days from December 16, 2020 (vaccine rollout date) to SARS-CoV-2 infection. For those with a prior SARS-CoV-2 infection positive tests within 90 days of the first positive test were considered part of the initial episode of illness. Employees that had not developed a SARS-CoV-2 infection were censored at the end of the study follow-up period (May 15, 2021). Those who received the Johnson & Johnson vaccine (81 subjects) without having had a SARS-CoV-2 infection were censored on the day of receipt of the vaccine, and those whose employment was terminated during the study period before they had SARS-CoV-2 infection (2245 subjects) were censored on the date of

termination of employment. The health system never had a requirement for asymptomatic employee test screening. Most of the positive tests, therefore, would have been tests done to evaluate suspicious symptoms. A small proportion would have been tests done as part of pre-operative or pre-procedural screening.

Statistical analysis

A Simon-Makuch hazard plot [11] was created to compare the cumulative incidence of SARS-CoV-2 infection among previously infected subjects who were vaccinated, with those of previously infected subjects who remained unvaccinated, previously uninfected subjects who were vaccinated, and previously uninfected subjects who remained unvaccinated. Previous infection was treated as a time-independent covariate (SARS-CoV-2 infection at least 42 days before Dec 16, 2020), and vaccination (14 days after receipt of the second dose of the vaccine) was treated as a time-dependent covariate (Figure 1). Curves for the unvaccinated were based on data for those who did not receive the vaccine over the duration of the study, and for those who did until the date they were considered vaccinated, from which point onwards their data were recorded into the corresponding vaccinated set. A Cox proportional hazards regression model was fitted with time to SARS-CoV-2 infection as the outcome variable against vaccination (as a time-dependent covariate whose value changed on the date a subject was considered vaccinated)[12]. Previous infection (as a time-independent covariate) and an interaction term for previous infection and vaccination were included as covariates. The phase of the epidemic was adjusted for by including the slope of the epidemic curve as a time-dependent covariate whose value changed continuously with the slope of the epidemic curve. The analysis was performed by NKS and ASN using the *survival* package and R version 4.0.5 [12–14].

RESULTS

Of 52238 employees included in the study, 2579 (5%) were previously infected with SARS-CoV-2.

Baseline characteristics

Those previously infected with SARS-CoV-2 were significantly younger (mean ± SD age; 39 ± 13 vs. 42 ± 13, $p<0.001$), and included a significantly higher proportion with patient-facing jobs (65% vs. 51%, $p<0.001$). Table 1 shows the characteristics of subjects grouped by whether or not they were previously infected. A significantly lower proportion of those previously infected (47%, 1220 subjects) were vaccinated by the end of the study compared to 58% (28855) of those not previously infected ($p<0.001$). Of those vaccinated, 63% received the Moderna vaccine. Twelve percent of subjects with previous SARS-CoV-2 infection did not have a symptom onset date, suggesting they may possibly have been identified on pre-operative or pre-procedural screening, and may not have had symptomatic infection. When vaccination was begun, the epidemic in Ohio was at the peak of its third wave (Figure 2).

Cumulative incidence of COVID-19

Figure 3 is a Simon-Makuch plot showing that SARS-CoV-2 infections occurred almost exclusively in subjects who were not previously infected with SARS-CoV-2 and who remained unvaccinated. The cumulative incidence of SARS-CoV-2 infection among previously infected unvaccinated subjects did not differ from that of previously infected subjects who were vaccinated, and that of previously uninfected subjects who were vaccinated. For all three of these groups, the cumulative incidence of SARS-CoV-2 infection was much lower than that of subjects who were not previously infected and who remained unvaccinated. Of the 2154 SARS-CoV-2 infections during the study period, 2139 (99.3%) occurred among those not previously infected who remained unvaccinated or were waiting

to get vaccinated, and15 (0.7%) occurred among those not previously infected who were vaccinated. Not one of the 2579 previously infected subjects had a SARS-CoV-2 infection, including 1359 who remained unvaccinated throughout the duration of the study.

Association of vaccination with occurrence of COVID-19

In a Cox proportional hazards regression model, after adjusting for the phase of the epidemic, vaccination was associated with a significantly lower risk of SARS-CoV-2 infection among those not previously infected (HR 0.031, 95% CI 0.015 – 0.061) but not among those previously infected (HR 0.313, 95% CI 0 – Infinity). The absence of events among those who were previously infected, whether they received the vaccine or not, precluded accurate or precise estimates for the latter effect size.

Duration of protection

This study was not specifically designed to determine the duration of protection afforded by natural infection, but for the previously infected subjects the median duration since prior infection was 143 days (IQR 76 – 179 days), and no one had SARS-CoV-2 infection over the following five months, suggesting that SARS-CoV-2 infection may provide protection against reinfection for 10 months or longer.

DISCUSSION

This study shows that subjects previously infected with SARS-CoV-2 are unlikely to get COVID-19 reinfection whether or not they receive the vaccine. This finding calls into question the necessity to vaccinate those who have already had SARS-CoV-2 infection.

It is reasonable to expect that immunity acquired by natural infection provides effective protection against future infection with SARS-CoV-2. Observational studies have indeed found very low rates of reinfection over the following months among survivors of COVID-19 [6–8]. Reports of true reinfections are extremely rare in the absence of emergence of new variants. When such reinfections occur, it would be purely speculative to suggest that a vaccine might have prevented them. Duration of protective immunity from natural infection is not known. However, the same also can be said about duration of protective immunity from vaccination. Uncertainty about the duration of protective immunity afforded by natural infection is not by itself a valid argument for vaccinating previously infected individuals. This study provides direct evidence that vaccination with the best available vaccines does not provide additional protection in previously infected individuals.

A prior study concluded that natural infection cannot be relied on to protect against COVID-19 [9]. That study was based on comparison of PCR-positivity rates during a second COVID-19 surge in Denmark between those who tested positive and negative during the first COVID-19 surge, and indirectly calculated that prior infection provided 80.5% protection against repeat infection, and that protection against those older than 65 years was only 47.1%. The study did not compare vaccinated and unvaccinated people, and it is therefore an assumption to consider that a vaccine would have provided better protection in that particular population. Furthermore, there was a gap of only seven weeks between the end of the first surge and the beginning of the second in that study. It is now well-known that a small number of people can continue to have positive PCR test results for several weeks to a few months after infection, one study finding that 5.3% remained positive at 90 days [15]. It is possible that some of the positives picked up in the early part of the second surge were not necessarily new infections but residual

virus from the tail end of the first surge. Since the actual number of infections was small, a few such misclassifications could change the rates substantially. Our study examined rates of SARS-CoV-2 infection in vaccinated and unvaccinated individuals and showed that those previously infected who did not receive the vaccine did not have higher rates of SARS-CoV-2 infection than those previously infected who did, thereby providing direct evidence that vaccination does not add protection to those who were previously infected.

There are several strengths to our study. Its large sample size and follow-up of up to 5 months provide us with an ample degree of confidence in its findings. A major strength of our study is that we adjusted the analyses for the phase of the epidemic at all time points. The risk of acquisition of infection is strongly influenced by the phase of the epidemic at any given time, and it is important to adjust for this for accurate risk analyses. Given that was this a study among employees of a health system, and that the health system had policies and procedures in recognition of the critical importance of keeping track of the pandemic among its employees, we had an accurate accounting of who had COVID-19, when they were diagnosed with COVID-19, who received a COVID-19 vaccine, and when they received it.

The study has its limitations. Because we did not have a policy of asymptomatic employee screening, previously infected subjects who remained asymptomatic might have been misclassified as previously uninfected. Given this limitation, one should be cautious about drawing conclusions about the protective effect of prior asymptomatic SARS-CoV-2 infection. It should be noted though, that 12% of the subjects classified as previously infected did not have a symptom onset date recorded, suggesting that at least some of those classified as previously infected might have been asymptomatic infections. It is reassuring that none of these possibly asymptomatically infected individuals developed COVID-19 during the duration of the study. The study follow-up duration was short, being only five months, but this was longer than published mRNA vaccine efficacy studies [1,2], and longer than the follow-up duration of the largest published vaccine effectiveness studies to date [3,4]. Median freedom from reinfection (time from initial infection until end of follow-up) in this study, for those previously infected, of almost 10 months, is consistent with findings in an earlier study that immunoglobulin G (IgG) to the spike protein remained

stable over more than six months after an episode of infection [16]. Our study included no children and few elderly subjects, and the majority would not have been immunosuppressed. Data governance policies in our institution precluded us from obtaining detailed clinical information on employees. While one cannot generalize this study's findings to assume that prior infection would provide adequate immunity in these groups, there is also no reason to expect a vaccine to provide additional protection in these same groups. Lastly, it is necessary to emphasize that these findings are based on the prevailing assortment of virus variants in the community during the study. It is not known how well these results will hold if or when some of the newer variants of concern become prominent. However, if prior infection does not afford protection against some of the newer variants of concern, there is little reason to suppose that the currently available vaccines would either. Vaccine breakthrough infections with variants have indeed been reported [17].

Our study's findings have important implications. Worldwide, COVID-19 vaccines are still in short supply. As of March 9, 2021, dozens of countries had not been able to administer a single dose of the vaccine [18]. As of May 17, 2021, only 17 countries had been able to reach ten percent or more of their populations with at least the first dose of vaccine [19]. Given such a scarcity of the vaccine, and the knowledge that vaccine does not provide additional protection to those previously infected, it would make most sense to limit vaccine administration to those who have not previously had the infection. In addition to profession, age, and comorbid conditions, previous infection should be an important consideration in deciding whom to prioritize to receive the vaccine. A practical and useful message would be to consider symptomatic COVID-19 to be as good as having received a vaccine, and that people who have had COVID-19 confirmed by a reliable laboratory test do not need the vaccine.

In conclusion, individuals who have laboratory-confirmed symptomatic SARS-CoV-2 infection are unlikely to benefit from COVID-19 vaccination, and vaccines can be safely prioritized to those who have not been infected before.

TRANSPARENCY DECLARATION

Conflict of Interest

Selection of "no competing interests" reflects that all authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organization for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

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Author contributions

NKS: Conceptualization, Methodology, Validation, Investigation, Data curation, Software, Formal analysis, Visualization, Writing- Original draft preparation, Writing- Reviewing and Editing, Supervision, Project administration.

ASN: Methodology, Formal analysis, Visualization, Validation, Writing- Reviewing and Editing.

PCB: Resources, Investigation, Validation, Writing- Reviewing and Editing.

PT: Resources, Writing- Reviewing and Editing.

SMG: Project administration, Resources, Writing- Reviewing and Editing.

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TABLES

Table 1. Study Subject Characteristics

Characteristic	Previously Infected (N = 2579)	Not Previously Infected (N = 49659)	*P* Value
Age, y, mean ± SD	39±13	42±13	<0.001
Patient-facing job	1676 (65)	25504 (51)	<0.001
Job location			<0.001
Cleveland Clinic Main Campus	1011 (39)	19595 (40)	
Regional hospitals	1096 (43)	16433 (33)	
Ambulatory centers	313 (12)	7767 (16)	
Administrative centers	138 (5)	4424 (9)	
Remote location	21 (<1)	1440 (3)	
Job category			<0.001
Professional staff	89 (4)	3775 (8)	
Residents and fellows	72 (3)	1669 (3)	
Advanced practice practitioners	154 (6)	2806 (6)	
Nursing	1142 (44)	13623 (27)	
Pharmacy	44 (2)	1274 (3)	
Research	328 (13)	6776 (14)	
Clinical support	111 (4)	3500 (7)	
Administration	614 (24)	15050(30)	
Administration support	25 (1)	1186 (2)	

Data are presented as no. (%) unless otherwise indicated

FIGURES

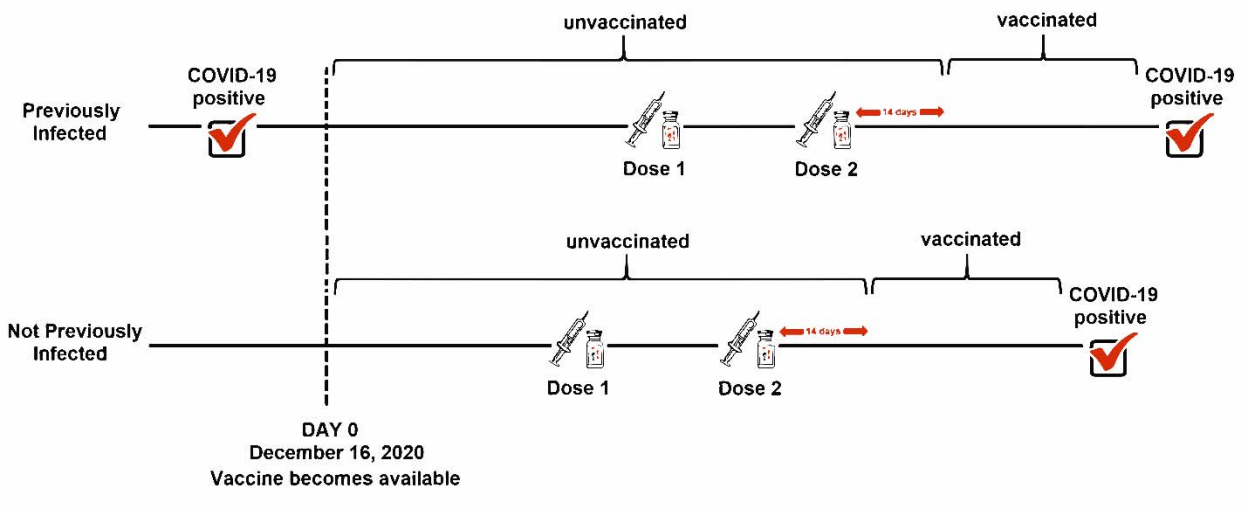

Figure 1. Explanation of "previously infected" analyzed as a time-independent covariate and "vaccinated" treated as a time-dependent covariate.

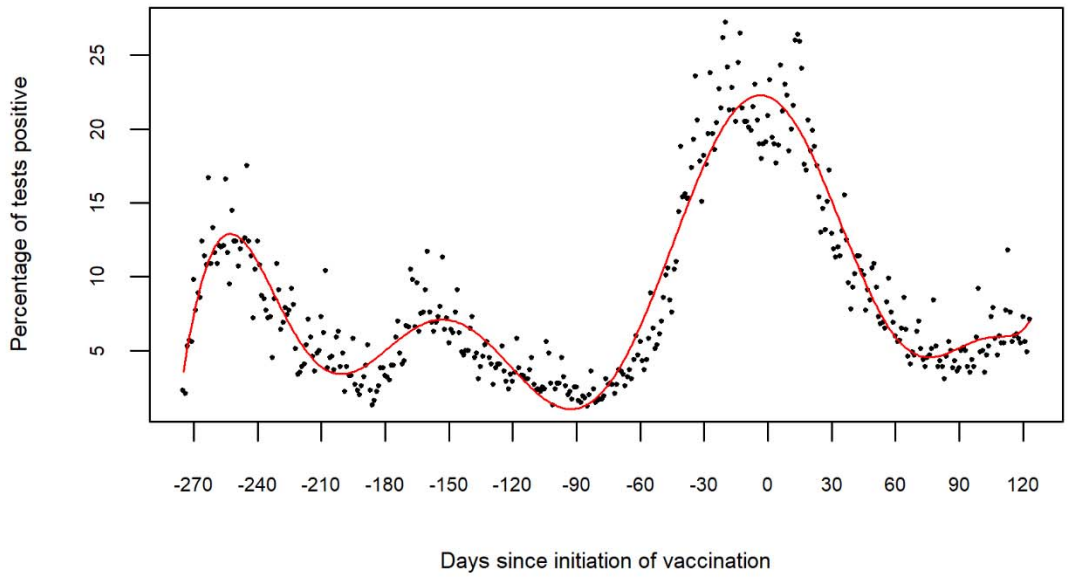

Figure 2. COVID-19 epidemic curve before and after vaccine rollout. Points on the scatter plot represent the proportion of all COVID-19 PCR tests done at Cleveland Clinic that were positive on any given day. The colored line represents a fitted polynomial curve.

EXHIBIT F

EXHIBIT F

CNN Interview with CDC Director Dr. Rochelle Walensky, during which Dr. Walensky indicates that *the vaccines no longer prevent transmission of COVID and should not be relied upon to do so*.

Discussion on this point can be found on Page 6 of this Transcript Exhibit.

THE SITUATION ROOM

CDC Says 100,000-Plus New COVID Cases Recorded Wednesday; Former DOJ Official Who Aided Trump Attempted Coup Facing New Scrutiny from House Investigation; New York State Cuomo Impeachment Probe Nears Completion; Interview with Arkansas Governor Asa Hutchinson on Regrets Over Signing Mask Mandate Ban. Aired 6-7p ET

Aired August 5, 2021 - 18:00 ET

THIS IS A RUSH TRANSCRIPT. THIS COPY MAY NOT BE IN ITS FINAL FORM AND MAY BE UPDATED.

[18:00:05]

WOLF BLITZER, CNN HOST: The CDC revealed today that information on deaths and hospitalization is incomplete. It's still unclear whether the new strain, the delta strain poses a greater threat to fully vaccinated Americans.

Just moments from now, I'll interview the CDC director, Dr. Rochelle Walensky. She is standing by live.

But, first, let's go to our Senior White House Correspondent Phil Mattingly for the late, breaking developments. Phil, how is the Biden administration responding to this devastating new wave of COVID?

PHIL MATTINGLY, CNN SENIOR WHITE HOUSE CORRESPONDENT: Wolf, for all of the different elements the federal government is trying to bring to bear to deal with this surge in cases, White House officials are unequivocal. There is one that matters more than any other, getting shots into arms. And they had seen some

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(BEGIN VIDEOTAPE)

MATTINGLY (voice over): Tonight, the White House ramping up its vaccination push as the U.S. passes 100,000 cases in a single day.

JEFF ZIENTS, WHITE HOUSE COVID-19 RESPONSE COORDINATOR: In seven states alone, Florida, Texas, Missouri, Arkansas, Louisiana, Alabama, Mississippi, states with some of the lowest vaccination rates, account for about half of new cases and hospitalizations in the past week, despite making up less than a quarter of the U.S. population.

MATTINGLY: A level that at one point seemed it would never be reached again. Yet with the delta variant surg gripping nearly the entire nation, a reality that's driven a return to a near singular daily focus, ramping up vaccinations.

DR. VIVEK MURTHY, U.S. SURGEON GENERAL: Today, I want to emphasize one fact that remains true, and that is the vaccines are working against the delta variant. MATTINGLY: Numbers that continue to tick upward with more 864,000 vaccinations on Wednesday, more than 560,000 first-time shots, the highest daily total in more than a month.

ZIENTS: Clearly, Americans are seeing the impact of being unvaccinated and unprotected, and they respond by doing their part, rolling up their sleeve and getting vaccinated.

MATTINGLY: But officials now acknowledging just how much remains unknown about the variant driving more than 90 percent of U.S. cases.

DR. ROCHELLE WALENSKY, CDC DIRECTOR: So, those data were data that were from analysis in several states from January through June and didn't reflect the data that we have now from the delta variant.

MATTINGLY: Revealing the actual data regarding hospitalizations and death for the vaccinated since delta surge hasn't been confirmed.

EXHIBIT F

I do want to reiterate though that based on the data we're seeing, we don't have fully updated numbers universally as we look at our hospitalizations and as we look at our deaths, they are overwhelmingly unvaccinated people.

MATTINGLY: But with more than 90 million eligible Americans still unvaccinated, renewed focus on other mitigation efforts specially masking and vaccine mandates has devolved once again into a pitched political battle.

GOV. RON DESANTIS (R-FL): What is his big solution? What is he so upset about Florida? His solution is he wants to have the government force kindergarteners to wear masks in school. I don't want to hear a blip about COVID from you.

MATTINGLY: The days' long back and forth between the White House and Florida Governor Ron DeSantis stil in effect.

JEN PSAKI, WHITE HOUSE PRESS SECRETARY: 25 percent of hospitalizations in the country are in Florida.

MATTINGLY: White House pointing to delta's surge in the state, making clear it has no plans to back down.

PSAKI: We're here to state the facts. Frankly, our view is that this is too serious, deadly serious, to be doing partisan name-calling. That's what we're not doing here.

(END VIDEOTAPE)

MATTINGLY (on camera): And, Wolf, the war of words between Florida Governor Ron DeSantis and the White House gas extended to the cabinet level as well. Education Department Secretary Cardona, today, saying in the briefing room, basically chastising Florida and Texas about mask mandates saying bluntly, don't be the reasons our kids can't go back to school. They have suffered enough. Wolf?

BLITZER: All right, Phil Mattingly, over at the White House. Thank you very much.

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appreciate what's going on.

You announced today that the CDC reported more than 103,000 new coronavirus cases just yesterday. What, six weeks ago, they were averaging about 11,000 or 12,000 cases a day, now more than 100,000 cases a day. What is the outlook right now? What are the next few weeks and months going to hold, because as you know, Dr. Walensky, a lot of nervous people out there, not just the unvaccinated but the vaccinated as well?

WALENSKY: Good evening, Wolf.

[18:05:00]

You know, what we're seeing in our projections demonstrates two different extremes. If we work together, unify as a country, vaccinate everyone who is interested in unvaccinated and put our masks on to prevent disease, we could really control this in a matter of weeks. However, our models show that if we don't do so, we could be up to several hundred thousand cases a day. It's similar to our surge in early January.

BLITZER: When do you think that would happen? Right now, let's say, 100,000 cases a day, as I said, six week ago, 11,000 cases a day, when will it be 200,000 or 300,000?

WALENSKY: I'm certainly hoping we don't have to see that. We don't want to see that. And so I'm really --- I'm opting for the let's unify as a country, put our masks on to prevent transmission of disease and get vaccinated in the interim. What I would say is, you know, we can see these kinds of exponential rises we're seeing now in a matter of weeks, but that's not where I'm heading?

BLITZER: What about deaths? You said today we saw 614 new deaths reported to the CDC just on Tuesday of this week. A few weeks ago, there were 100, 200, now more than 600. What does it look like as far as deaths ar concerned, deaths of Americans in the coming weeks and months?

WALENSKY: This is a critically important point one. When we have seen this number of cases before, we have seen far more deaths. And what that means is that our vaccines are working to prevent deaths. So, they're working to prevent hospitalizations and they're working to prevent deaths among those who are vaccinated. So the best way to stop those deaths from happening is to get vaccinated.

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Will we start to see case counts drop again anytime soon? WALENSKY: We have not seen that yet. We're still seeing exponential rises in Florida, in many -- in Louisiana and many of the southern states that are seeing these surges. And so, no, we're not quite there yet. And I certainly hope that now we're taking these matters seriously. I'm grateful to the governor of Louisiana who put forward masking and mask mandates and I want to encourage others, either leaders or to have the American public, pull together and wear their mask to prevent infecting others.

BLITZER: What are your models saying, Dr. Walensky, about the northeast, for example, where vaccination levels are clearly higher? Should those states expect to see surges due to this awful delta variant as well?

WALENSKY: We know how to protect ourselves. Many of those places are vaccinated in the areas that have pockets of people who are unvaccinated. Again, we would encourage this will happen at the community level. So we would encourage vaccination across those areas so that we don't have pockets of surges around areas that might have been undervaccinated in the northeast region.

BLITZER: There are some things I would like to clear up while I have you, Dr. Walensky. In terms of communication, you clearly have data that's informing your decisions or you wouldn't be making these decisions. But a lot of experts are asking, why aren't you sharing that data right away or at least releasing it more quickly?

WALENSKY: Last Tuesday, we made the decision to advice masking America among those who are fully vaccinated, and that was decision based on data that we had seen just several days before and corroborated within hours or a couple of days before. We made those recommendations based on data.

We had -- the data were released on Friday, just three days later. And if we had waited to release the data, we would have had, you know, people who would unknowingly potentially bring virus to their loved ones, to their immunosuppressed loved ones. We felt it a moral imperative to inform the American public as soon as we knew and publish the data as soon as we could within three days of our guidance.

BLITZER: Yes. So that's really important to get that information out there. Do you think the CDC and others, for example, got the messaging wrong when it comes to breakthrough cases, people who are fully vaccinated but get COVID? Experts have insisted that breakthrough cases are rare, almost dismissing fears. But wouldn't it

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WALENSKY: I think we all have to recognize that with 164 million people who are vaccinated, we should expect tens of thousands, perhaps, of breakthrough infections. But the most important thing, it is not the numbe of the breakthrough infections but what happens here.

Those breakthrough infections have mild illness. They are staying out of the hospital. They are not dying. And I think that that's the most important thing to understand. We have a massive number of people who are vaccinated and those breakthrough infections tend to be mild and not severe.

BLITZER: But what about all the fully vaccinated people who get the breakthrough infection? Can they pass it on? Could they pass it on to their children? Could they pass the virus on to older people, especially more vulnerable people with underlying health conditions?

WALENSKY: And that's exactly the point that we made in our guidance.

[18:10:00]

So, yes, they can with the delta variant. And that was the reason that we changed our guidance last Tuesday. Ou vaccines are working exceptionally well. They continue to work well with delta with regard to severe illness an death. They prevent it.

But what they can't do anymore is prevent transmission. So if you are going home to somebody who has not been vaccinated to somebody who can't get vaccinated, somebody who might be immunosuppressed or a little bit frail, somebody who has co-morbidities that put them at high risk, I would suggest you wear a mask in public indoor settings.

BLITZER: Especially if there is a breakthrough case and you get COVID, you're fully vaccinated but you are totally asymptomatic, you can still pass on the virus to someone else. Is that right?

WALENSKY: That's exactly right. And that's where our masking recommendation came from.

BLITZER: It's so important these mask.

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of us who got two shots we might need after five or six months a third shot?

WALENSKY: We're looking at those data carefully. Those data include looking at clinical cohorts, our clinical trials, cohorts from across the country, our essential workers, long term-care facilities, health care workers who were vaccinated early. And we're working closely with the FDA following those data and we'll come up with a plan soon in September.

BLITZER: And do you think that before that will happen, the emergency use authorization for these vaccines will be changed to complete and full authorization?

WALENSKY: That lies squarely with the FDA. But I know that they're working very hard in order to get that full approval because I recognize that -- we all recognize that some people are waiting for that approval to get vaccinated.

BLITZER: So, what we're seeing in Israel, Germany and the United Kingdom right now, people are already starting or about to start getting these third booster shots. We could brace for that, we should anticipate that happening in the next few weeks here in the United States. Is that right?

WALENSKY: We're having conversations with those countries and we're looking at the same data that they are looking at and we are making our independent decisions looking at the data they have, collaborating with the data we have and we'll make those decisions in collaboration with the FDA.

BLITZER: All right. Well, I'm anxious to get my third shot if that's going to help. I'm sure a lot of people are anxious to get their third shot as well.

Why has the messaging from the CDC, Dr. Walensky, and other health experts for that matter on boosters at least, so far, been unclear? First, we were told we wouldn't need boosters. Then we were told information was coming. Other experts have said there is no evidence to support needing a booster. It's all been rather confusing.

WALENSKY: We are following the science. There is immunologic data. Some people are following the immunologic data and are reporting on the immunologic data. There is effectiveness data from those cohort studies across the nation, tens of thousands of people. We have not yet seen a signal that we require boosters

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So, we're looking at many different areas and everybody is assessing the science. As that science evolves, we will report that science to the American people.

BLITZER: 12 million Americans got the Johnson & Johnson single dose vaccine. If they get a booster, will it b Johnson & Johnson or Moderna or Pfizer?

WALENSKY: Those data are going to live with the FDA right now. They are looking at the data on what we're calling crossover studies, whether what you got the first time, you would get the same thing or a different vaccine. Those data are with the FDA right now.

BLITZER: So that hasn't been determined yet.

You have often said, Dr. Walensky, that what, 99 percent of the coronavirus deaths, 95 percent of the hospitalizations are among the unvaccinated. But when you were asked today by our Chief White House Correspondent Kaitlan Collins, you said those numbers were from January through June, June, and didn't reflec the data we have now from the delta variant, which I'm told by experts is entirely different than the older variants, very highly transmissible, much more deadly. Do you have updated data that includes the delta variant

WALENSKY: We're working closely with the states and in touch with them in terms of their reporting. There was a terrific Kaiser Family Foundation analysis that was done, including 25 states that suggested that those data still hold, that over 99 percent of hospitalizations, over 99.9 percent of deaths still are in unvaccinated people in these hospitals. BLITZER: So, when do you think we could expect to see the new data on breakthrough hospitalizations and deaths? We're talking about fully vaccinated Americans in light of the delta variant. And does it closely reflect the statistics you have been citing that almost entirely all the hospitalizations and deaths are among unvaccinated?

WALENSKY: All of the data that I have seen to date have demonstrated that the severe disease, hospitalizations and deaths associated with COVID-19, even with the delta variant have suggested over 99 percent, the vast majority of people are unvaccinated, which is why it is so very important to get the people vaccinated.

[18:15:15]

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WALENSKY: You know, as the data come in, as we update the data, not all of our inpatients, for example, have a genomic sequence associated with their test, so we're continually updating the data. It's a very fluid situation.

BLITZER: How does the communication strategy evolve? Because there is a real serious problem out there, at least right now, and hopefully it will go away, of confusion. A lot of us are confused by what we're hearing, different things all the time.

WALENSKY: The American public wants certainty. I want certainty. I think we all want certainty. We want to understand the path forward. And I completely understand that. My job is to evaluate the science. The science every single day, hundreds of papers are being posted that evaluate the immunogenicity of our vaccines, how they are working, the epidemiology of the delta variant both here and around the world. My job is to update that science and to communicate that to the American people.

BLITZER: I know Dr. Fauci said that about 93 million Americans right now are still unvaccinated. Do we know of that 93 million how many actually had COVID and have some antibodies built in? Do they need those who already had COVID, do they need to get these two shots?

WALENSKY: Importantly, yes, they do. So we know that the breadth and depth of your immune response is far expanded when you get the vaccine and that it is important to get vaccinated even if you had COVID. You may have had a different variant. We know now that your rates of getting COVID again are higher if you have not been vaccinated.

BLITZER: And so do we know how many of the 93 million actually had COVID?

WALENSKY: We have data, zero prevalence data across the nation, but I don't know that we can match the people who have been unvaccinated with the zero prevalence data.

BLITZER: With 96.1 percent of the U.S. population in areas which are described as high or substantial transmission that are subject to updated masking guidelines indoors, are changes coming to the recommendations from the CDC on masking outdoors as well?

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are going to see immunocompromised people in crowded settings, consider wearing a mask. And we don't anticipate those changes any time soon.

BLITZER: So even if you are in a baseball game or an outdoor concert, will you should still be wearing a mask if there is a big crowd around you? Is that what I'm hearing?

WALENSKY: If you are in a big crowd and you are unvaccinated, absolutely. And if you are vaccinated, we're leaving that to personal discretion.

BLITZER: Dr. Fauci also says that even worse, an even worse -- this is awful to hear this -- an even worse coronavirus variant could be coming beyond delta. Is there a specific variant you're watching right now with concern?

WALENSKY: We're watching numerous variants as they emerge. I don't have one that is more concerning right now in addition to delta. What I can say though is that the more we have viral replication, the more we have transmission, the more we are at risk of a new and emerging variant, and that is why it is so very critical to get vaccinated not just for yourself, for your own personal health, to protect you from severe disease and death but to protect you from transmission to others as well as to protect all of us from seeing a more aggressive emerging variant.

BLITZER: I'm so worried about a new variant that's even worse than delta. And the question is, Dr. Walensky, will our current vaccines hold up against the next, the next variant?

WALENSKY: That's, of course, the concern. And we will have to see what this virus brings. What I can say is that the virus generally mutates and those mutations hold because it is advantageous to the virus. So our job nov is to squash the virus and to do so by decreasing chains of transmission through vaccination and masking in the interim.

BLITZER: Among the vaccinated right now, the fully vaccinated and, you know, that's a huge part of the country, are there populations within the fully vaccinated, Dr. Walensky, who are a more vulnerable right now?

WALENSKY: Among the fully vaccinated, certainly those who are most immunosuppressed, we know that thei

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[18:20:04]

We know that those people, despite having been fully vaccinated, they received two doses, may not have complete protection.

BLITZER: Is there any update on when kids, children under 12, will be able to get vaccinated?

WALENSKY: So those data are, of course, going to be with the FDA. I haven't seen them and I'm looking forward to when we will see them hopefully in the next, you know, several months, in the fall. You know, hopefully in the fall before the end of the calendar year.

BLITZER: And I have heard that we're talking about kids 5 to 11 who will be next in line to start getting vaccinated. Is that right?

WALENSKY: Indeed. And in the meantime, please know that the best way to protect your unvaccinated children is to surround them with vaccinated people.

BLITZER: And to wear masks even if you are vaccinated potentially, right?

WALENSKY: In public indoor settings so that you can shed it when you come home.

BLITZER: As children across the nation are returning and preparing to return to school right now, is an increase in cases around the country, Dr. Walensky, inevitable?

WALENSKY: I think it's really clear that we know how to keep our children safe. We know how to keep our schools safe. Disease comes into the schools from high rates in the community. We know how to keep our community safe. Our children deserve to have full-time in person safe learning with prevention measures in place, and that includes masking for everyone in schools.

BLITZER: Are you getting any early data from places like Georgia, for example, where schools are back in session right now, are you getting any new information already coming in, or is it too early?

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summer schools and where places did not enforce mitigation strategies, masking, those are the summer schools that had a challenge and had to close down.

BLITZER: What is your reaction to the Florida governor's decision to prevent schools throughout the state of Florida from mandating masks, warning they would be denied state funding if they were to do so?

WALENSKY: I'm a physician. I want our children to be safe. I want them to be safe wherever they live. The best way to keep them safe is to surround them by vaccinated people and to have them where masks in school. I want our kids back to school and I want them back safely, and I want them to be able to safely stay there.

BLITZER: Me too. I think everybody watching wants the kids to be safe in the most effective way.

When did the president, Dr. Walensky, first approach you guys over at the CDC about finding ways to extend what's called the eviction moratorium following the U.S. Supreme Court decision in June? There are a lot of nervous people out there who are fearful that they're going to be kicked out of their homes and become homeless.

WALENSKY: As we have seen the case counts go up and knowing that this eviction moratorium end date was going to impose hundreds of thousands of people were going to have to find congregate settings to live in, we decided to update a new -- well, actually provide a new tailored eviction moratorium so that our places where there was the most disease would not be an increased public health risk by having all of these families and people need to find shelter in congregate settings.

BLITZER: So, there are millions of Americans who have not even gotten one shot right now. What is your message to them? Are there any of those millions who shouldn't be getting a vaccine right now? What's the downside of potentially getting a vaccine?

WALENSKY: My message to those people is to get the information you need. Get it from a trusted source, get i from somebody who understands the science behind it because I do think that if you talk to the people who understand the science, who are trusted to you, you will not need to be convinced to get the vaccine. You will b asking for it.

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WALENSKY: No, only that we are here for you, we are here for the health of the public, we are asking people to get the information that they need to get vaccinated. This is a difficult, hard, frustrating time. We share that frustration, and we are updating the science and will convey it to you as soon as we have it.

BLITZER: And should we be bracing for the situation to get worse before it gets better?

WALENSKY: I think we should be bracing for a unified nation that can come together and realize that the common foe is COVID-19.

BLITZER: It certainly is. And we're so appreciative, Dr. Walensky, for all you-- for all of what you and your teams are doing. We are grateful to you. Thank you so much for joining us.

WALENSKY: Thanks for having me.

BLITZER: Just ahead, we're learning more about a key U.S. Justice Department official who actually aided former President Trump's attempt to try to stage a coup during his final days in office.

[18:25:05]

Stay with us. You're in The Situation Room.

(COMMERCIAL BREAK) BLITZER: Last hour, President Biden and Vice President Harris honored the brave men and women who put their lives on the line to defend the U.S. Capitol on January 6th. The president held a ceremony in the White House Rose Garden where he signed an act awarding the officers a congressional gold medal.

This as multiple sources are now telling CNN that the January 6th select committee in the House of Representatives is moving to consolidate all congressional investigations into the insurrection.

Our Justice Correspondent Jessica Schneider is joining us right now with more.

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Jessica, what can you tell us?

JESSICA SCHNEIDER, CNN JUSTICE CORRESPONDENT: You know, Wolf, it isn't uncommon for a select committee to really consolidate all of the work of these committees, so there is not a turf battle, if you will. But what this does mean is that the interviews of the former Acting Attorney General Jeffrey Rosen and his Deputy Richard Donoghue, they will now be delayed. They were expected to happen this week.

And, of course, Rosen and Donoghue, they are expected to eventually give crucial insight into how a Trump ally within the Justice Department, Jeffrey Clark, pushed other top DOJ officials to back those false claims of election fraud.

(BEGIN VIDEOTAPE)

JEFFREY CLARK, FORMER ASSISTANT ATTORNEY GENERAL: Good morning. I'm Jeff Clark. I'm the head of the Civil Division.

SCHNEIDER: Jeffrey Clark was in charge of a Department at DOJ that would have had no role investigating voter proud. But in the weeks after the election, Clark seemed to cozy up to Trump by parroting the president's false claims of fraud.

DONALD TRUMP, FORMER U.S. PRESIDENT: That was a rigged election.

SCHNEIDER: And pushing the Justice Department to step in.

REP. GERRY CONNOLLY (D-VA): Jeffrey Clark, you're a subordinate at DOJ, reportedly told you that your days as acting attorney general were numbered and that DOJ was going to stop Congress from certifying the election results, is that true?

JEFFREY ROSEN, FORMER ACTING U.S. ATTORNEY GENERAL: Congressman, the items you are talking about, I have seen media accounts.

SCHNEIDER: Jeffrey Rosen has never publically confirmed the intense pressure campaign coming from Clark

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December 28, 2020 details how Clark planned to write Georgia officials to falsely say DOJ had found voting irregularities that impacted the election outcome in several states. He wanted Rosen and Rosen's deputy, Richar Donoghue, to sign on, but they flat-out refused with Donoghue responding by email, there is no chance that I would sign this letter or anything remotely like this. From where I stand, this is not even within the realm the possibility.

DAVID LAUFMAN, FORMER DOJ CHIEF OF COUNTERINTELLIGENCE: It signifies how perilously clos we came to the Department of Justice being weaponized.

SCHNEIDER: Clark's draft letter was dated December 28th, one day after Trump called Rosen and Donoghue, telling them, just say the election was corrupt and leave the rest to me and the Republican Congressmen, according to hand written notes of the exchange. Days later, Trump was on the phone with Georgia's secretary of state pleading.

TRUMP: All I want to do is this. I just want to find 11,780 votes, which is one more than we have.

REP. ADAM SCHIFF (D-CA): I certainly hope that the U.S. Justice Department, as well as Georgia officials, are studying the president's conduct because it seems to cross the line into illegality.

SCHNEIDER: There is no known federal investigation of Trump or Clark, but former Assistant U.S. Attorney Elie Honig laid out the possible crimes both could hypothetically be charged with.

ELIE HONIG, CNN SENIOR LEGAL ANALYST: It is a federal crime to deprive a state of a fair election. It is a federal crime to solicit false counting of ballots, false certification of an election. It is a federal crime to conspire against the United States.

(END VIDEOTAPE)

SCHNEIDER (on camera): But for now, any criminal charges are extremely unlikely with Congress taking the lead on this investigation of this issue.

And as for Jeffrey Clark, there is no indication he's facing any backlash in the legal community since he was jus

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But, Wolf, we reached out to his representative. He is declining to comment on any of this.

And as for the investigation here, the Senate Judiciary Committee chairman, Dick Durbin, he says that he does want Jeffrey Clark to testify before his committee. No word on when.

BLITZER: Yes. I suspect he will be at least subpoenaed if he doesn't voluntarily want to show up. All right, Jessica, thank you very much.

Let's discuss this with our Chief Political Correspondent Dana Bash, our Chief Legal Analyst Jeffrey Toobin and our Senior Legal Analyst, Laura Coates.

Jeffrey, as a former Federal Prosecutor yourself, how outrageous was this behavior by Jeffrey Clark to essentially attempt a coup from inside the U.S. Justice Department?

JEFFREY TOOBIN, CNN CHIEF LEGAL ANALYST: You know, it is really bad but it is not nearly as bad as what his boss, his ultimate boss, Donald Trump, did. I think Jeffrey Clark was simply acting out the abuse of power that the president was engaged in.

You know, what's gone on here with the president is so much like what he did when he told the president of Ukraine that he should come up with dirt on President Biden or lose government money. I'm not sure it's a crime. I don't think any of this, frankly, is criminal in nature. But it would have been impeachable if the president stayed in office and I think it's an abuse of presidential power, which is, in many respects, more important than a crime.

BLITZER: Well, Laura Coates, what do you think?

LAURA COATES, CNN SENIOR LEGAL ANALYST: Well, I think it's outrageous that somebody who would not even oversee elections or voting as the head of the civil division, I was in the civil rights division in the voting section at one point in my career.

[18:35:08]

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anything but that.

The good news here is that his superiors decided that they were not going to do that, that they refused to do so, that they weren't going to be essentially those who are going to be the vehicles of misinformation in this respect

But what's very troubling here is that the goal was to plant the seeds that ultimately were germinated by people, that ultimately still for people who either when they're looking at the attack on the citadel of our democracy on January 6th or to this day still very much believe that this election was stolen, he was effective in that respect to try to perpetuate it.

And that, you know, it is always this gap, as Jeffrey talked about, between what is criminal and what ought to be illegal. Surely it is unethical. He knew better. We know that in a court of law they would never have promoted these theories because there was no basis. And don't take my word for it. Take the former attorney general, William Barr, who himself said he saw no evidence of widespread voter fraud or otherwise.

BLITZER: Yes. That's exactly right.

You know, Dana, we saw the effort, the violent effort to try to overturn the election unfold during the January 6th insurrection but there was a quiet effort going on behind the scenes inside the Justice Department.

DANA BASH, CNN CHIEF POLITICAL CORRESPONDENT: Yes. And, I mean look, they were very much connected, as Laura was just saying, that what was going on inside the Justice Department was, no doubt, at the behest of the president of the United States.

What happened on January 6th was because of what the president of the United States and those around him were perpetuating, a lie that they were perpetuating up until and including that day, that rally on January 6th. So they are very much connected. They are just different avenues that people who were doing the now former president's bidding were going down.

And, you know, what is interesting about what Jessica was reporting about, the fact that Congress as the select committee and the fact that they're going to try to interview these individuals that we have been reporting on, that that might be why DOJ, the Biden Justice Department, will hold off on even considering whether there is

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I mean, what Congress has to do is get information for the historical record. They don't have the ability to criminally prosecute. That is DOJ. It might just kick the can down the road a little bit. But it doesn't -- I don't think, unless their legal colleagues think so that they're mutually exclusive.

BLITZER: Well, let me bring Jeffrey back into this conversation. Jeffrey as you know, a lot of Democrats they're looking to the Attorney General Merrick Garland to investigate this, restore integrity over the Department of Justice. Does he need to take a more aggressive approach here?

TOOBIN: Well, I certainly think there is no problem with an investigation. But, you know, one -- everything we are outraged by is not a crime. And I think, you know, it is very important if you believe in civil liberties to limi criminal violations, limit the prosecution of criminal violations to actual, provable violations of federal law.

I'm not sure that Jeffrey Clark's letter -- in fact, I would be surprised if that is a violation of any criminal law. It is outrageous. It should be condemned. But I think we need to keep a clear line between what's criminal and what's merely outrageous. And the Justice Department, at least so far, seems very determined to do that.

BLITZER: Laura?

COATES: And, you know, on that thought, if I could, you know, one way to find out if there is truly criminal behavior and violations of our federal law is through discovery, in interviews. And what the DOJ, the Justice Department has done essentially through Merrick Garland, excuse me, has been to say, we're not even going to assert the executive privilege that would effectively muzzle those people who would have the information, who could lead that determination. They decided they're not going to assert executive privilege, which normally has been a roadblock that says, you might want transparency, but we don't have to give it to you. It could include nc only Jeffrey Rosen and other people involved in this chain of communication. But including there was a U.S. attorney in the state of Georgia who abruptly resigned. Is there a correlation to this big lie that was promoted by this person as well? Then you have an even bigger story.

So we are really at a premature level now to decide that it is not criminal and the investigation should unfold to figure out if it, in fact, is. But either way, the DOJ is not putting up a roadblock that was up in full effect just a few months ago.

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he can get these people to go to court.

[18:40:02]

And if they go to court, it could delay their testimony for months, and that may be as good as stopping it altogether.

BLITZER: All right. Jeffrey, thank you. Laura and Dana, thanks to you guys as well.

Coming up, the New York governor, Andrew Cuomo, is yet to resign. But as pressure mounts, is a resignation near? Stay with us. You're in The Situation Room.

(COMMERCIAL BREAK)

BLITZER: The New York State impeachment investigation into Governor Andrew Cuomo appears to be nearing a conclusion. Let's get some more from CNN's Erica Hill. Erica, how quickly could Governor Cuomo be impeached?

[18:45:00]

ERICA HILL, CNN NATIONAL CORRESPONDENT: The short answer is pretty quickly. So, as you point out a letter was sent today to Governor Cuomo's attorneys, noting that the Judiciary Committee's impeachment investigations are nearing completion and inviting the governor's attorneys to submit any additional evidence that they would like.

Now, we know that the deadline for submitting that additional evidence is next Friday, August 13th, 5:00 p.m. So articles obviously won't be introduced before that.

I can tell you that we earned earlier this week from an assembly speaker who said that everything that develope on Tuesday in that AG's report meant they were going to move expeditiously to conclude this investigation as soon as possible. Now, both the governor's attorney and his director of communications responding to that letter said this morning, they both side they would cooperate. We're grateful for the opportunity, essentially, to

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AG's report accusing the investigators acting as prosecutor, judge and jury rather than independent fact finders.

WOLF BLITZER, CNN HOST: Is there any indication, Erica, that Governor Cuomo will resign? Because this certainly seems like, at least for now, that he's digging in.

HILL: Yeah, I think you hit the nail in the head. I think he is digging in. We see that in a response from his attorneys. We know there have been a number of public calls for him to resign. A lot of people telling him he should not go through this impeachment process.

We learned a little bit about what some of those conversations may have been like behind the scenes. Jay Jacobs, the head of the state's Democratic Party, sharing the governor's response to his conversation with him when he urged the governor to resign.

Take a listen.

(BEGIN VIDEO CLIP)

JAY JACOBS, NEW YORK DEMOCRATIC COMMITTEE CHAIR: He didn't characterize, you know, his views on resignation. He was more directed to how he was going to defend himself. I think he feels that he wants his moment to tell the public his side of the story.

(END VIDEO CLIP)

HILL: Jay Jacobs saying that taped statement the governor put out on Tuesday after the AG's report was released likely didn't land the way he thought it would and perhaps his team. But interesting to note there that the governor in the phone call with Jay Jacobs was more focused on his defense, on telling what he referred to as his side of the story. I think we got a little sense of that in that taped statement and even in some of the statements we saw today.

BLITZER: All right. Erica, thank you very much.

Let's get some analysis from the Washington correspondent for "The New York Times", Maggie Haberman.

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Maggie, is it resign or face impeachment at this point, or does Governor Cuomo think he has other options to cling to power? Because any support he thinks he might have seems to be crumbling.

MAGGIE HABERMAN, CNN POLITICAL ANALYST: Wolf, if there was an impeachment vote today, Governor Cuomo would be impeached and pushed out through a Senate trial that I cannot imagine he would want to go through. It's not today. So, I think he is gong to try to roll the dice and hang on as long as he can, and hope that he can change some lawmakers' minds. That seems very unlikely just based on the statements that we have seen, and just based on the crumbling of support, nearly universal that has taken place among his key supports, black leaders, union leaders, a number of state assembly officials, among Democrats and every Republican would vote in favor of impeachment.

So, it is hard to see how buying time is going to help him. It is not surprising that's what he's doing unlike, Wolf in 2002 when he dropped out of the race for governor a couple of days before the Democratic primary, that he was going to lose. He still had a future, and so that was his calculation in doing that.

He does not have a political future now. He is a much older man. There are not many options. That report is seen as very damning.

And so, I think he will ride this out as soon as possible. The prospect of being impeached I think is devastating to him. I think as it gets closer, if the facts don't change, if he can't corral any lawmakers to his side, then I think it is more than likely that he'll resign.

BLITZER: Nixon decided that he would resign rather than get impeached and convicted.

HABERMAN: Right.

BLITZER: The letter says the New York state assembly will consider potential articles of impeachment. How quickly could the dominos fall once that happens?

HABERMAN: It really depends, Wolf. It could happen fairly quickly. There could be a vote within several days of that happening. There's a push by Republicans to try to have various probes that are going on into the New York governor. It takes place in this impeachment probe at the same time, or at least be part of the same

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But it could happen very quickly. Remember, there is no hard and fast rule in New York state's laws about how this impeachment process would go. They get to sort of make it up as they go along. Again, I don't think that Andrew Cuomo will stick it out for a trial. I think when there is a vote nearing is when you will see a potential breaking report.

BLITZER: According to the report released this week, Governor Cuomo never bothered to complete his own sexual harassment training program, while at the same time he was harassing women, touting himself as a leade on this issue.

[18:50:10]

Does that speak to how he operates?

HABERMAN: What I think it speaks to is a culture in that office. Again, I do want to say, you'd have to read th report. I think he says he doesn't remember whether that's true. It speaks to the fact that there is an important aspect of I think it's gotten overlooked a lot.

It isn't that he's accused of harassing multiple women, 11 women working in his office. It's that he created a workplace culture of toxicity after passing laws against such a thing. So, it wasn't just that he was harassing, is that he was violating his own laws, to your point.

I don't know it speaks to how he operates necessarily. I think it speaks to the fact that he was more than willing to act as if -- actually he was more than willing to put into place laws that essentially, according to this report, h was not willing to follow along with, and refer other people. The idea that you would have a subordinate fill out and complete training that you have subjected other people to in their workplace speaks volumes about, you know, sort of how he views power.

Now, again, he has denied all this. I am really curious to see what their denials are, because they keep stressing emphatically that they're going to have them. What we saw is frankly, we're not much of a defense at all. So, we'll see where this goes.

BLITZER: We certainly will.

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Just ahead, the Arkansas Governor Asa Hutchinson is standing by. He will join us live. We will discuss the worst of the coronavirus surge and the role mask can play in fighting it.

We'll be right back.

(COMMERCIAL BREAK)

[18:55:53]

BLITZER: The coronavirus pandemic is surging all across the United States with the CDC now reporting more than 100,000 cases in a single day and the situation is especially dire in places with low vaccination rates. For that and more, I want to bring in the governor of Arkansas, Asa Hutchinson.

Governor, thank you so much for joining us.

As you know, the coronavirus transmission is soaring in your state right now. You say you regret signing a bill earlier this year that banned mass requirements in schools. So, why did you think putting a ban in place was a good idea? What are you doing now to correct that mistake?

GOV. ASA HUTCHINSON (R-AR): Well, at the time that we put that law into place, that banned mask mandates but also vaccine passports, our cases were very, very low. It looked like we were at the end of this pandemic. I felt comfortable at the time signing it.

And obviously, this virus threw us another curve. The delta variant came in. Our cases have gone up. And now we're looking at going back to school, and our focus is on the vaccines. But there is still a gap there, because under 12 cannot be vaccinated. We need some method and flexibility from local school districts to protect them So I called the general assembly back into session and the governor to

address this gap and ask them to give flexibility to local school districts, so if they decided to cover those that are under 12 that can't be vaccinated with face coverings, to protect them, then that's their prerogative. That is a local decision-making.

EXHIBIT F

tomorrow and it's also in the courts being reviewed as to whether that law is constitutional.

So we'll see how this develops tomorrow. But that's the reason I called them back into session.

BLITZER: Well, it's a good reason, because this delta variant, as you know, is highly, highly transmissible. Much worse than the original virus.

What's your message, Governor, to some of your fellow Republican governors who are fueling misinformation about simply wearing a mask, including the Florida Governor Ron DeSantis, who has gone so far as to threaten to pull funding from local school districts that actually would institute mask mandates?

HUTCHINSON: Well, Wolf, I'm not getting into what's happening in Florida. That's the beauty of our system, that every state and governor manages it with their legislature and it reflects the culture of their state.

So, I just got a look at what we are doing here in Arkansas and this made common sense to me. One, promoting vaccines, we've got to get those out. That's the first level. Secondly, there is the gap again.

And my judgment is that's a conservative view that local school districts out to be able to make decisions, themselves. Some of the rural ones will say, no, we don't need that. Other urban school districts, they want to have more protection. They might adopt that protective measure and they ought to have the right to do that. It's very simple. That's the approach.

BLITZER: But if they want to go ahead and mandate masks, you wouldn't pull state funding to those school districts, would you?

HUTCHINSON: Well, no. I mean, again, I believe they ought to have that prerogative particularly whenever they're under 12.

But that's -- that's local control. Whenever you are looking at -- I think the debate we're getting off track here, the debate right now is on masks and it shouldn't be. It ought to be on the work of getting vaccines out. That's the number one --

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HUTCHINSON: -- priority that I have. But we got that gap we got to cover.

BLITZER: And you want everyone in Arkansas to get vaccinated, right? HUTCHINSON: Well, absolutely. I've gone to I believe it's 12 cities. I

will be going to two more cities next week having conversations for those that doubt, have questions, honesty. We're not shaming anybody, providing good information.

BLITZER: That's so, so important. It could save a lot of live.

Governor Asa Hutchinson from Arkansas, thanks so much for joining us always. You are always welcome to THE SITUATION ROOM.

And to our viewers, thanks for watching.

"ERIN BURNETT OUFRONT" starts right now.

EXHIBIT F

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